



**Table 1. Hemovigilance Module Annual Facility Survey (CDC 57.300)**

For all questions, use information from previous full **calendar** year.

| Data Field  | Instructions for Form Completion   |
|---|--|
| Facility ID#  | The NHSN-assigned Facility ID number will be auto entered by the system.   |
| Survey Year   | Required. Enter the most recent previous calendar year. For example, if you are completing this survey in February 2008 the survey year will be 2007.  |
| <b>Facility Characteristics</b>                       |  |
| 1. Ownership  | Required. Check the ownership type that most closely represents your facility.   |
| 2. Is your hospital affiliated with a medical school? | Required. Check <b>Yes</b> if your hospital is associated with a medical school.   |
| Type of affiliation                                   | Conditionally required. If Yes, select type of affiliation:<br><b>Major</b> affiliation:<br><ul style="list-style-type: none"> <li>• Training programs 1 year in length, <u>each</u> resident would spend 2 months at the affiliate institution</li> <li>• Training programs 2 years in length, <u>each</u> resident would spend 4 months at the affiliate over the 2 year period</li> <li>• Training programs 3 or more years in length, <u>each</u> resident would spend at least 6 months at the affiliate over the entire training period.</li> </ul> <b>Graduate</b> affiliation:<br>The facility is affiliated with the medical school only for its graduate programs and one or more is in effect:<br><ul style="list-style-type: none"> <li>• House staff of the Graduate Medical Education (GME) are selected by officials of a medical school department or by a joint committee of the institution teaching staff and medical school faculty</li> <li>• Medical school faculty (other than the institution's attending staff) is regularly scheduled to participate in the teaching programs of the institution. No graduate affiliation is indicated if medical school faculty participation is limited to an occasional lecture or consultation visit, or if the institution's residents attend medical school teaching conferences only as visitors</li> <li>• A contractual arrangement specifies the medical school participation in the organization and supervision of the GME program in the institution</li> <li>• There is some degree of exchange of residents between this institution and the principal teaching institution of the medical school.</li> </ul> <b>Limited</b> affiliation:<br>The facility is affiliated with a medical school's teaching program only for brief/unique rotations of students/residents. |



| Data Field   | Instructions for Form Completion   |
|--|--|
| 3. Community setting of facility   | Optional. Check the setting that most closely describes the location of your facility.<br><b>Urban:</b> Areas classified as a Metropolitan Statistical Area by the U.S. Census Bureau; each area must have at least one urbanized area of 50,000 or more inhabitants.<br><b>Suburban:</b> Areas classified as a Micropolitan Statistical Area by the U.S. Census Bureau; each Micropolitan statistical area must have at least one urban cluster of at least 10,000 but less than 50,000 inhabitants.<br><b>Rural:</b> Areas classified as Balance of County by the U.S. Census Bureau; there are no urban areas of at least 10,000 inhabitants. |
| 4. Total facility beds set up and staffed and served by Transfusion Services   | Required. Total inpatient beds in the facility served by your department.  |
| 5. Number of surgeries performed per year  | Required. Inpatient and outpatient surgeries performed at your facility in the past full calendar year.  |
| 6. At what trauma level is your facility certified?  | Required. Indicate the trauma level (1, 2, 3, 4, NA) of your facility.   |
| Transfusion Services Characteristics   |  |
| 7. Primary classification of facility areas served by Transfusion Services.  | Required. Check all that apply.  |
| 8. Is your Transfusion Services part of the facility's core laboratory?  | Required. Check <b>Yes</b> if your transfusion service functions as a part of the core laboratory rather than as an independent department.  |
| 9. How many dedicated Transfusion Services staff members are there?  | Required. Consider 2 part-time workers as a single full time equivalent (FTE). Include supervisors. Technical FTEs include MLTs and MTs.   |
| 10. Does your hospital have a dedicated position or FTE in a quality or patient safety department/function for investigation of transfusion-related adverse reactions? | Required. Dedicated: One individual (or FTE) is responsible for overseeing the investigation of all transfusion-related adverse reactions. Medical director, managers, supervisors, or others within the Transfusion Service executive management should not be included.  |
| 11. Does your hospital have a dedicated position or FTE in a quality or patient safety department/function for investigation of errors (i.e. incidents)?               | Required. Dedicated: One individual (or FTE) is responsible for overseeing the investigation of all transfusion errors. Medical director, managers, supervisors, or others within the Transfusion Service executive management should not be included.   |
| 12. Is your Transfusion Services lab accredited?   | Required. If <b>Yes</b> , check appropriate accrediting organization(s).   |



| Data Field  | Instructions for Form Completion   |
|---|--|
| 13. How is your hospital accredited?                                    | Required. Check the organization that accredits your facility.   |
| 14. Do you have a committee that reviews blood utilization?             | Required. Check <b>Yes</b> if a formal committee has been established that meets regularly to review blood utilization.  |
| 15. Total number of samples collected?                                  | Required. The total number of samples collected for type and screen or crossmatch in the <u>previous calendar year</u> .   |
| 16. Products and total number of units/aliquots transfused              | Required. Check each product type transfused <b>in the past full calendar year</b> . Provide the total number of units and/or aliquots transfused in the past calendar year of each selected type. For each product type selected, the total number of units and aliquots (if applicable) must be >0. Do not include the units from which the aliquots were made in your unit count. |
| Whole blood derived red blood cells                                     | Conditionally required. If checked, enter the number of units and/or aliquots transfused. If no units or aliquots were transfused, enter 0.  |
| Apheresis red blood cells   | Conditionally required. If checked, enter the number of units and/or aliquots transfused. If no units or aliquots were transfused, enter 0.  |
| Whole blood derived platelet concentrates                               | Conditionally required. If checked, enter the number of units transfused, regardless of the pool size that created the unit. For example, a 6 pool unit would equal 1 unit transfused.   |
| What is your average pool size?   | Conditionally required. If WBD platelet concentrates is checked, enter the average pool size of transfused units.  |
| Apheresis platelets   | Conditionally required. If checked, enter the number of units and/or aliquots transfused. If no units or aliquots were transfused, enter 0.  |
| Whole blood derived plasma (include FFP, thawed, etc.)                  | Conditionally required. If checked, enter the number of units and/or aliquots transfused. If no units or aliquots were transfused, enter 0.  |
| Apheresis plasma  | Conditionally required. If checked, enter the number of units and/or aliquots transfused. If no units or aliquots were transfused, enter 0.  |
| Cryoprecipitate   | Conditionally required. If checked, enter the number of units transfused.  |
| Granulocytes  | Conditionally required. If checked, enter the number of units and/or aliquots transfused. If no units or aliquots were transfused, enter 0.  |
| Lymphocytes   | Conditionally required. If checked, enter the number of units and/or aliquots transfused. If no units or aliquots were transfused, enter 0.  |
| 17. Are any of the following administered through Transfusion Services? | Required. Check all products that are maintained and ordered through your department or check <b>None</b> .  |



| Data Field  | Instructions for Form Completion   |
|---|--|
| 18. Does your facility attempt to transfuse only leukocyte-reduced cellular components?               | Required. Check <b>Yes</b> if it is <u>facility policy</u> to transfuse only leukocyte-reduced cellular components, even if some products are transfused that are not leukocyte-reduced.   |
| 19. Units transfused by department or service   | Optional. Please provide the number of samples collected and units and/or aliquots transfused by department or service.  |
| 20. Are all units stored in the Transfusion Services area?  | Required. If some units are routinely stored in other parts of your facility check <b>No</b> .   |
| Locations of satellite storage  | Conditionally required. If <b>No</b> , check facility location(s) where units may also be stored.  |
| 21. To what extent does Transfusion Services modify products?   | Required. Check only the processes that are performed within your department and facility.   |
| 22. Do you collect blood for transfusion at your facility?  | Required. Check <b>Yes</b> if your facility performs blood collection in-house.  |
| Type of blood collection  | Conditionally required. If <b>Yes</b> , check all that apply.  |
| 23. Does your facility perform viral testing on blood for transfusion?                                | Required. If viral testing is performed, but not in-house, check <b>No</b> .   |
| <b>Transfusion Services Computerization</b>   |  |
| 24. Is Transfusion Services computerized?   | Required. If your department uses an electronic system for <u>any</u> part of the blood product issuing process, answer <b>Yes</b> . If <b>No</b> , skip to the next section.  |
| System(s) used  | Conditionally required. If <b>Yes</b> , Check all systems used in the Transfusion Services department.   |
| 25. Is your system ISBT-128 compliant?  | Conditionally required. Check <b>Yes</b> , if the Transfusion Services department uses the ISBT-128 code system for unit labeling.   |
| 26. Does the Transfusion Services system interface with the patient registration system?              | Conditionally required. Check <b>Yes</b> if the Transfusion Services computer system directly accesses the patient registration system (i.e., electronic interface and exchange of information).   |
| 27. Are Transfusion Services adverse events entered into a hospital-wide electronic reporting system? | Conditionally required. Check <b>Yes</b> , if adverse events, including adverse reactions and/or medical incidents, reported to or occurring within your department are entered into a system that is used across your facility (as opposed to a system that is maintained entirely within your department). |
| 28. Do you use positive patient ID technology for Transfusion Services?                               | Conditionally required.  |
| For what purpose(s)?  | Conditionally required. If <b>Yes</b> , check all that apply.  |
| System(s) used  | Conditionally required. If <b>Yes</b> , check all that apply.  |



| Data Field   | Instructions for Form Completion  |
|--|---|
| 29. Do you have online order entry for test requesting?  | Conditionally required. Check <b>Yes</b> if a physician can enter orders for laboratory testing directly into a computer system.  |
| 30. Do you have physician online order entry for product requesting?   | Conditionally required. Check <b>Yes</b> if a physician can directly order blood and blood products through a computer system.  |
| <b>Transfusion Services Specimens Handling and Testing</b>   |   |
| 31. Are the Transfusion Services specimens drawn by a dedicated phlebotomy team?   | Required. Indicate the frequency with which samples for transfusion services are drawn by dedicated phlebotomy staff as opposed to patient care area staff or other staff.                |
| 32. What specimen labels are used at your facility?  | Required. Indicate the type(s) of labels used for patient identification on the sample tube.  |
| 33. Is phlebotomy staff allowed to correct errors on pre-transfusion specimen labels?  | Required. Check <b>Yes</b> if phlebotomy staff members are allowed to manually correct name spelling, medical record number, etc. on the specimen label at the time of sample collection. |
| 34. What items can be used to verify patient identification during specimen collection and prior to product administration?                  | Required. Check all pieces of information that can be used to verify patient identification as specified in your hospital policy.   |
| 35. How are routine type and screen done?  | Required. Check all that apply.   |
| Frequency?   | Conditionally required. Estimate the frequency for each method checked. The total of the three percentage fields should be 100.   |
| 36. Is the ABO group of a pre-transfusion specimen routinely confirmed?  | Required.   |
| Under what circumstances?  | Conditionally required. If <b>Yes</b> , check one.  |
| Is the confirmation required on a separately-collected specimen before a unit of Group A, B or AB red blood cells is issued for transfusion? | Conditionally required. Check <b>Yes</b> if a separately-collected specimen is required for confirmation prior to transfusion of Group A, B, or AB red blood cells.                       |
| 37. How many RBC type and screen and crossmatch procedures were performed at your facility by any method?                                    | Required. Enter the number of RBC type and screen and RBC crossmatch procedures that were performed in the past full calendar year.   |
| Crossmatch method frequency.   | Required. Estimate the frequency of each method by which crossmatch was performed. Total can be >100%.  |



**Table 2. Hemovigilance Module Monthly Reporting Plan (CDC 57.301)**

| Data Field  | Instructions for Form Completion  |
|---|---|
| Facility ID#  | The NHSN-assigned Facility ID number will be auto entered by the system.  |
| Month   | Required. Indicate the month for the reporting plan being entered.  |
| Year  | Required. Indicate the year for the reporting plan being entered.   |
| Adverse transfusion reactions and all incidents associated with reactions | Required. (Auto selected) Participation in the Hemovigilance Module requires reporting of all transfusion reactions and incidents known or suspected as being associated with a transfusion reaction.   |
| Monthly reporting denominators  | Required. (Auto selected) Participation in the Hemovigilance Module requires reporting of the total number of blood products (units and aliquots) transfused each month.  |
| Method of incident reporting  | <p>Required. Select the method of incident reporting for the month.</p> <p><b>Summary data with detailed reporting of high priority incidents:</b> Totals will be reported for all incidents that occur during the month. Detailed incident reports will only be entered for high priority incidents and incidents associated with transfusion reactions.</p> <p><b>Detailed reporting of all incidents:</b> Detailed incident reports will be entered for every incident that occurs during the month.</p> |



**Table 3. Hemovigilance Module Blood Product Incidents Reporting–Summary Data (CDC 57.302)**

| <b>Data Field</b>                                 | <b>Instructions for Form Completion</b>  |
|---|--|
| Facility ID#                                      | The NHSN-assigned Facility ID number will be auto entered by the system.   |
| Month   | Required. Indicate the month for the summary record being entered.   |
| Year  | Required. Indicate the year for the summary record being entered.  |
| Process Code                                      | Required. Select Process Code. It is only necessary to add rows for incident types that occurred during the month.   |
| Incident Code                                     | Required. Select Incident Code. It is only necessary to add rows for incident types that occurred during the month.  |
| Total Incidents                                   | Required. Enter the total number of incidents for each incident code selected. <b>Include detailed incident reports in your totals.</b> High priority incidents and incidents associated with transfusion reactions require detailed incident reports. |
| Total Adverse Reactions associated with Incidents | Required. Enter the total number of adverse reactions that were observed for each incident code. A detailed incident report must be entered for each. If no adverse reactions were associated with reported incidents, enter 0.                        |
| Total   | Required. The system automatically totals each column.   |



**Table 4. Hemovigilance Module Monthly Reporting Denominators (CDC 57.303)**

| <b>Data Field</b>                   |                                  | <b>Instructions for Form Completion</b>  |
|-------------------------------------|----------------------------------|--|
| Facility ID#                        |                                  | The NHSN-assigned Facility ID number will be auto entered by the system.   |
| Month                               |                                  | Required. Enter the month for which you are reporting.   |
| Year                                |                                  | Required. Enter the year for which you are reporting.  |
| <b>Product</b>                      |                                  | <b>Units and Aliquots Transfused</b>   |
| Whole blood derived Red blood cells | Total                            | Required. Enter the total number of units and aliquots of whole blood derived (WBD) red blood cells (RBCs) transfused during the month that were irradiated (only), leukocyte reduced (only), irradiated and leukocyte reduced, and not modified by any of those methods. If none, enter 0. Do not include the units from which the aliquots were made in your unit count. |
|                                     | Irradiated                       | Required. Enter the number of units and aliquots of irradiated (only) WBD RBCs that were transfused during the month. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.   |
|                                     | Leukocyte reduced                | Required. Enter the number of units and aliquots of leukocyte reduced (only) WBD RBCs that were transfused during the month. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.  |
|                                     | Irradiated and leukocyte reduced | Required. Enter the number of units and aliquots of WBD RBCs transfused during the month that were both irradiated and leukocyte reduced. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.   |
| Apheresis Red blood cells           | Total                            | Required. Enter the total number of units and aliquots of apheresis RBCs transfused during the month that were irradiated (only), leukocyte reduced (only), irradiated and leukocyte reduced, and not modified by any of those methods. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.                                   |
|                                     | Irradiated                       | Required. Enter the number of units and aliquots of irradiated (only) apheresis RBCs that were transfused during the month. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.   |
|                                     | Leukocyte reduced                | Required. Enter the number of units and aliquots of leukocyte reduced (only) apheresis RBCs that were transfused during the month. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.  |
|                                     | Irradiated and leukocyte reduced | Required. Enter the number of units and aliquots of apheresis RBCs transfused during the month that were both irradiated and leukocyte reduced. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.   |



| Data Field                    |                                  | Instructions for Form Completion  |
|-------------------------------|----------------------------------|---|
| Whole blood derived Platelets | Total                            | Required. Enter the total number of units of WBD platelets transfused during the month that were irradiated (only), leukocyte reduced (only), irradiated and leukocyte reduced, and not modified by any of those methods. If none, enter 0.   |
|                               | Irradiated                       | Required. Enter the number of units of irradiated (only) WBD platelets that were transfused during the month. If none, enter 0.   |
|                               | Leukocyte reduced                | Required. Enter the number of units of leukocyte reduced (only) WBD platelets that were transfused during the month. If none, enter 0.  |
|                               | Irradiated and leukocyte reduced | Required. Enter the number of units of WBD platelets transfused during the month that were both irradiated and leukocyte reduced. If none, enter 0.   |
| Apheresis Platelets           | Total                            | Required. Enter the total number of units and aliquots of apheresis platelets transfused during the month that were irradiated (only), leukocyte reduced (only), irradiated and leukocyte reduced, and not modified by any of those methods. If none, enter 0. Do not include the units from which the aliquots were made in your unit count. |
|                               | Irradiated                       | Required. Enter the number of units and aliquots of irradiated (only) apheresis platelets that were transfused during the month. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.   |
|                               | Leukocyte reduced                | Required. Enter the number of units and aliquots of leukocyte reduced (only) apheresis platelets that were transfused during the month. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.  |
|                               | Irradiated and leukocyte reduced | Required. Enter the number of units and aliquots of apheresis platelets transfused during the month that were both irradiated and leukocyte reduced. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.   |
| Plasma (all types)            | Total whole blood derived        | Required. Enter the total number of units and aliquots of all types (fresh frozen, thawed, etc.) of WBD plasma that were transfused during the month. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.  |
|                               | Total apheresis                  | Required. Enter the total number of units and aliquots of all types (fresh frozen, thawed, etc.) of apheresis plasma that were transfused during the month. If none, enter 0. Do not include the units from which the aliquots were made in your unit count.  |
| Cryoprecipitate               |                                  | Required. Enter the total number of units of cryoprecipitate (all types) transfused during the month. If none, enter 0.   |
| Total samples collected       |                                  | Required. Enter the total number of blood samples collected for type and screen and/or crossmatch during the month.   |
| Custom Fields                 |                                  | Optional. Up to five numeric fields may be added to this form for local use. Each Custom Field must be added to the form in NHSN before it can be selected for use.   |



**Table 5. Hemovigilance Module Adverse Reaction (CDC 57.304)**

| Data Field                                    | Instructions for Form Completion   |
|---|--|
| Facility ID#                                  | The NHSN-assigned Facility ID number will be auto entered by the system.   |
| Adverse Reaction #                            | This NHSN-assigned adverse reaction number will be auto entered by the system.   |
| <b>Patient Information</b>                    |  |
| Patient ID                                    | Required. Enter the medical record number or other facility alphanumeric identification code for the patient.  |
| Gender  | Required. Select the gender of the patient.  |
| Date of birth                                 | Required. Enter the date of birth of the patient.  |
| Blood group                                   | Required. Select the blood group for the patient (recipient).<br><i>Note: Some patient blood types do not fall clearly into these categories. If this is the case, select the most relevant blood type and note the issue in the comments section of the form. For example, if a patient is typing with mixed field reactions following a bone marrow transplant, select the predominant type and enter a note in the comments section such as this: Group A recipient of group O bone marrow transplant, currently typing as mixed field.</i> |
| Primary underlying reason for transfusion     | Required: Enter the primary reason this patient received a transfusion, e.g., malignancy, trauma, transplantation, surgery (other than transplantation), internal bleeding, genetic disorder (e.g. sickle cell disease), hemolysis, etc. Be as specific as possible in the space provided. Avoid using "anemia," as it does not adequately describe the underlying condition.  |
| <b>Reaction Details</b>                       |  |
| Date reaction occurred                        | Required. Enter the date the reaction was first observed in the patient.   |
| Time reaction occurred                        | Required. Enter the time the reaction was first observed in the patient.   |
| Facility location where reaction occurred     | Required. Enter the facility location of the patient at the time the reaction was first observed.  |
| Is this reaction associated with an incident? | Required. Check <b>Yes</b> if this reaction is associated with one or more incidents.  |
| If Yes, Incident #:                           | Conditionally required. If this reaction is associated with an incident, enter the NHSN-assigned incident number. A reaction may be associated with more than one incident.<br><i>Note: In order to link an adverse reaction to an incident in NHSN, the incident record must be entered into the system first and must include the Patient ID. When you attempt to link the adverse reaction record, NHSN will search for a matching Patient ID# in the incident records.</i>   |



| Data Field                         | Instructions for Form Completion   |
|------------------------------------|--|
| Signs and symptoms, laboratory     | Required. Check <b>all</b> signs and symptoms observed in the patient at the time the reaction occurred as well as any associated laboratory findings. These may or may not be directly related to the observed reaction as patients receiving transfusions typically have underlying medical conditions. See Appendix A in the Hemovigilance Module protocol for a glossary of terms.   |
| <b>Component Details</b>           |  |
| Transfusion Date                   | Required. Enter the date each component transfusion began.   |
| Transfusion Time                   | Required. Enter the time each component transfusion began.   |
| Component code (check system used) | Required. Select the labeling system used for these components.  |
| Component code                     | <p>Required. Enter the ISBT-128 or Codabar code for the type of component administered. Use only the part of the code that identifies the product type. Enter all components administered within 24 hours prior to an acute transfusion reaction. For delayed transfusion reactions, enter the component(s) most likely responsible for the reaction based on temporal relationship and clinical judgment.</p> <p>In the example ISBT-128 label below, the code that identifies the product type is E0472.</p> <div data-bbox="641 1165 917 1396" style="text-align: center;">  <p>E0472V00</p> <p>WASHED<br/>RED BLOOD CELLS<br/>IRRADIATED</p> <p>From 450 mL Whole Blood<br/>Store at 1 to 6 C</p> </div> <p><i>Note: When you enter the component code into NHSN, a product description will appear. If the code entered does not match a product description in the NHSN master list, "Component code not found" will appear in the product description field. Verify your data entry before continuing, though an unrecognized component code will not prevent you from saving the adverse reaction record.</i></p> |
| # of units                         | <p>Required. Enter the total number of units of each product type administered to the patient. If a particular unit was implicated in the adverse reaction, enter that unit on its own line so that additional information specific to that unit can be entered. Additional units can be entered in the following rows, using the worksheet on page 4 if necessary.</p> <p><i>Note: Add rows as needed when entering into NHSN.</i></p>  |



| Data Field                          | Instructions for Form Completion   |
|-------------------------------------|--|
| Unit number                         | <p>Conditionally required. Unit number is required for TRALI, GVHD, and infections. Unit number is optional for all other adverse reactions.</p> <p>Enter the individual unit number as it appears on the product label.</p> <p>For example, this sample ISBT-128 unit number would be entered in the following manner:</p>  <p>W 0 0 0 0<br/>0 7<br/>1 2 3 4 5 6<br/>0 0<br/>D</p> <p><i>Note: The check digit is optional. If the check digit is entered, the system will verify that it is correct using an internal check digit calculator. If the check digit is not entered, the space will remain blank.</i></p> |
| Unit expiration date                | <p>Required. Enter the expiration date of the unit(s). The expiration date for the sample label below would be 02/11/2007.</p>    |
| Unit expiration time                | <p>Required. Enter the expiration time of the unit(s). NHSN will auto fill this editable field to 23:59. The expiration time for the sample label below would be 15:20.</p>   |
| Blood group of unit                 | <p>Required. Select the blood group of the unit(s) administered to the patient or enter <b>N/A</b> for products where blood group is not applicable.</p>   |
| Implicated in the adverse reaction? | <p>Conditionally required. If a single unit was identified as the probable cause of the reaction, check this box for the implicated unit. The unit must be entered on its own line, and the number of units checked can only be 1. Multiple units cannot be checked. If the patient received multiple units and it is not clear which one caused the reaction, do not check this box for any of the listed components.</p>   |



| Data Field  | Instructions for Form Completion  |
|---|---|
| <b>Investigation Results</b>  |   |
| Was a particular unit implicated in the adverse reaction?                                   | Required. This data field can only be <b>Yes</b> if an implicated unit was selected in the Component Details section. If an implicated unit was not identified, select <b>No</b> .  |
| Adverse reaction  | Required. Select the adverse reaction for which you are reporting. Only one adverse transfusion reaction can be reported on a single form. Refer to the case definition criteria in Appendix A of the Hemovigilance Module protocol to categorize the reaction.<br><i>Note: Report the reaction <b>after the investigation has been finalized</b>. Incomplete records cannot be saved. If additional information becomes available, the record can be edited.</i> |
| Allergic reaction, including anaphylaxis  |   |
| Acute hemolytic transfusion reaction (AHTR)   |   |
| Type of AHTR  | Conditionally required. Indicate whether the AHTR was immune-mediated or non-immune mediated. If immune-mediated, specify antibody. If non-immune-mediated, specify cause.  |
| Delayed hemolytic transfusion reaction (DHTR)   |   |
| Type of DHTR  | Conditionally required. Indicate whether the DHTR was immune-mediated or non-immune mediated. If immune-mediated, specify antibody. If non-immune-mediated, specify cause.  |
| Delayed serologic transfusion reaction (DSTR)   |   |
| DSTR antibody   | Conditionally required. Specify antibody.   |
| Febrile non-hemolytic transfusion reaction (FNHTR)  |   |
| Hypotensive transfusion reaction  |   |
| Infection   |   |
| Type of infection   | Conditionally required. Select the type of infection being reported (bacterial, viral, other).  |
| Specify organism  | Conditionally required. Select up to three organisms.   |
| Was a test to detect a specific antigen performed on the <b>recipient</b> post-transfusion? | Conditionally required. Indicate whether or not a test was performed on the <b>recipient</b> to detect a specific pathogen after the blood product(s) was (were) administered to the recipient.   |
| Positive/Reactive?  | Conditionally required. If a post-transfusion test was performed, indicate whether it was positive or reactive.   |
| Specify organism  | Conditionally required. If a post-transfusion test was performed and found to be positive or reactive, indicate the detected organism. Select up to three organisms.  |
| Was a test to detect a specific antigen performed on the <b>donor</b> post-donation?        | Conditionally required. Indicate whether or not a test was performed on the <b>donor</b> to detect a specific pathogen after the blood donation was collected.  |



| Data Field  | Instructions for Form Completion  |
|---|---|
| Positive/Reactive?  | Conditionally required. If a post-donation test was performed, indicate whether it was positive or reactive.  |
| Specify organism  | Conditionally required. If a post-donation test was performed and found to be positive or reactive, indicate the detected organism. Select up to three organisms.   |
| Was a test to detect a specific antigen performed on the <b>unit</b> post-transfusion?                                      | Conditionally required. Indicate whether or not a test was performed on the <b>implicated blood product</b> to detect a specific pathogen after the blood product(s) was (were) administered to the recipient.  |
| Positive/Reactive?  | Conditionally required. If a post-transfusion test was performed, indicate whether it was positive or reactive.   |
| Specify organism  | Conditionally required. If a post-transfusion test was performed and found to be positive or reactive, indicate the detected organism. Select up to three organisms.  |
| Post transfusion purpura (PTP)  |   |
| Transfusion-associated circulatory overload (TACO)  |   |
| Transfusion-associated dyspnea (TAD)  |   |
| Transfusion-associated graft vs. host disease   |   |
| Did the patient receive non-irradiated blood product(s) in the two months preceding the reaction?                           | Conditionally required.   |
| Transfusion-related acute lung injury (TRALI)   |   |
| Antibody studies performed  | Optional. If antibody studies were performed on the donor and/or the recipient, enter the results.  |
| Unknown pathophysiology<br><i>The patient experienced transfusion-related symptoms, but the cause was never determined.</i> |   |
| Other (specify)<br><i>The recipient was diagnosed with an adverse reaction that is not described in the protocol.</i>       |   |
| Case definition criteria  | Required. Using the case definitions in the Hemovigilance Module protocol, select the criteria met for the reported adverse reaction.   |
| Grade   | Required. Using the severity criteria in the Hemovigilance Module protocol, select the grade of the adverse reaction.   |
| Relationship (Imputability)   | Required. Using the imputability criteria in the Hemovigilance Module protocol, select the imputability of the reaction.<br><i>Note: <b>Doubtful</b> or <b>Ruled Out</b> should only be used if, after the initial record was entered, new information resulted in downgrading imputability from definite, probable, or possible.</i> |
| Outcome   |   |
| Outcome   | Required. Enter the outcome of the recipient.   |
| Date of death   | Optional. If the recipient died, enter the date of death whether or not the death was transfusion related.  |



| <b>Data Field</b>                    | <b>Instructions for Form Completion</b>   |
|--------------------------------------|---|
| Relationship of transfusion to death | Conditionally required. If the recipient died after the adverse transfusion reaction, indicate the relationship of the transfusion to death using the imputability descriptions defined in Appendix C of the Hemovigilance Module protocol. |
| Custom Fields                        | Optional. Up to two date fields and ten alphanumeric fields may be added to this form for local use. Each Custom Field must be added to the form in NHSN before it can be selected for use.   |
| Comments                             | Optional. Enter additional information about the adverse reaction.  |



**Table 6. Hemovigilance Module Incident (CDC 57.305)**

| <b>Data Field</b>   | <b>Instructions for Form Completion</b>   |
|---|---|
| Facility ID#  | The NHSN-assigned Facility ID number will be auto entered by the system.  |
| NHSN Incident #   | This NHSN-assigned incident number will be auto entered by the system.  |
| Local Incident # or Log #   | Optional. Enter your facility's incident report, log, or other locally-assigned incident number.  |
| <b>Discovery</b>  |   |
| Date of discovery   | Required. Enter the date the incident was discovered. It should be the same or later than the date of occurrence. The date must fall within the monitoring month.   |
| Time of discovery   | Required. Enter the time the incident was discovered. If the exact time is not known, enter an approximate time and check the "Time approximate" box. If the time cannot be determined, select "Time unknown."  |
| Where in the facility was the incident discovered?                      | Required. Enter the facility-defined NHSN location code for the physical location where the incident was discovered. This may or may not be the same as where the incident occurred.  |
| How was the incident <b>first discovered</b> ?                          | Required. Select the description most closely represents how the incident <b>first discovered</b> . If "Other" is selected, briefly describe how the incident was discovered.   |
| At what point in the process was the incident <b>first discovered</b> ? | Required. Select the process point at which the incident was <b>first discovered</b> . This may or may not be the same process point at which the incident occurred.  |
| <b>Occurrence</b>   |   |
| Date incident occurred  | Required. Enter the date the incident occurred. This must be on or before the date of discovery.  |
| Time incident occurred  | Required. Enter the time the incident occurred. If the exact time is not known, enter an approximate time and check the "Time approximate" box. If the time cannot be determined, select "Time unknown."  |
| Where in the facility did the incident occur?                           | Required. Enter the facility-defined NHSN location code for the physical location where the incident occurred. This may or may not be the same as where the incident was discovered.  |
| Job function of the worker involved in the Incident                     | Optional. Enter the <u>job function</u> of the worker involved in the incident using the codes on page 5 of the form. This is the worker who was involved in and may have been responsible for the incident at the time that it occurred. This is not necessarily the person who discovered the incident. |
| At what point in the process did the incident <b>first occur</b> ?      | Required. Select the process point in the process where the incident first occurred.  |
| Incident Code   | Required. Enter the NHSN Incident code that describes the incident you are reporting. Incident codes are found on page 4  |



| Data Field  | Instructions for Form Completion  |
|---|---|
|   | of the form. If no incident code exists for the incident you are reporting, use MS 99 and briefly describe the incident.  |
| Incident summary                                      | Optional. Provide a description of the incident. It is not recommended that you use names of the employees or patients involved; use generic descriptions such as: nurse, patient, physician, etc. Only 500 characters are allowed.   |
| Incident result                                       | Required. Select the outcome of the incident.   |
| No recovery, harm                                     | Product was transfused and the patient experienced an adverse reaction.   |
| No recovery, no harm                                  | Product was transfused, but the patient did not experience an adverse reaction.   |
| Near miss, unplanned recovery                         | Product was not transfused. The incident was discovered ad hoc, by accident, by a human lucky catch, etc.   |
| Near miss, planned recovery                           | Product was not transfused. The incident was discovered through a standardized process or barrier built into the transfusion process to prevent errors.   |
| Product action  | Required. Check all that apply.   |
| Not applicable  | The incident occurred before a product was selected.  |
| Product retrieved                                     | The blood product or component involved in the incident was intercepted or withdrawn and was not transfused to the patient.   |
| Product destroyed                                     | The blood product or component was destroyed as a result of the incident that is being reported.  |
| Code system used                                      | Conditionally required. If product or component was destroyed, select the labeling system used for the product destroyed.   |
| Single or multiple units destroyed?                   | Conditionally required. If product or component was destroyed, indicate whether single or multiple units were destroyed.  |
| Single unit   | Conditionally required: If a single unit was destroyed, enter the individual unit number or the component code.   |
| Multiple unit   | Conditionally required. If multiple units were destroyed, enter the component code(s) and the total number of units for each.   |
| Product issued but not transfused.                    | The blood product was issued to the patient care area, but was NOT transfused.  |
| Product transfused                                    | The blood product was transfused.   |
| Was a patient reaction associated with this incident? | Conditionally required. If the blood product involved in the incident was transfused, indicate whether the patient(s) experienced an adverse transfusion reaction.  |
| Patient ID#(s)  | Conditionally required. If a transfusion reaction occurred, enter their Patient ID#(s). Multiple patients can be listed.<br><i>Note: In order to link an adverse reaction to an incident in NHSN, the incident record must be entered into the system first and must include the Patient ID. When you attempt to link the adverse reaction record, NHSN will search for a matching Patient ID# in the incident records.</i> |



| Data Field  | Instructions for Form Completion  |
|---|---|
| Record/other action   | Required. Select all applicable follow-up actions that were performed in response to this incident. If <b>Other</b> is selected, briefly describe the action.                               |
| <b>Investigation Results</b>  |   |
| Did this incident receive root cause analysis?  | Required. Indicate whether a formal, documented root cause analysis of the incident was performed.  |
| If YES, result(s) of analysis   | Conditionally required. If a root cause analysis was performed, select all applicable results. If <b>Other</b> is selected, briefly describe the results.                                   |
| <p><b>Technical:</b></p> <ul style="list-style-type: none"> <li>• Technical failures beyond the control and responsibility of the facility</li> <li>• Failure due to poor design of equipment, software, labels or forms</li> <li>• Correct design but not constructed properly or set up in in-accessible areas</li> <li>• Other material defects</li> </ul>   |   |
| <p><b>Organizational:</b></p> <ul style="list-style-type: none"> <li>• Failure at an organizational level beyond the control and responsibility of the facility or department where the incident occurred</li> <li>• Failure resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff</li> <li>• Failure relating to the quality and availability of the protocols/procedures within the department (e.g., too complicated, inaccurate, unrealistic, absent or poorly presented)</li> <li>• Internal management decisions when faced with conflicting demands or objectives. Failures resulting from collective approach and its attendant modes of behavior to risks in the investigating organization. These are organizational cultural attitudes and behaviors.</li> </ul>  |   |
| <p><b>Human:</b></p> <ul style="list-style-type: none"> <li>• Human failures originating beyond the control and responsibility of the investigating organization. This could include individuals in other departments</li> <li>• Inability of an individual to apply their existing knowledge to a novel situation.</li> <li>• The incorrect fit between an individual's training or education and a particular task.</li> <li>• A lack of task coordination within a health care team.</li> <li>• Incorrect or incomplete assessment of a situation including related conditions of the patient and materials to be used before starting the transfusion. Faulty task planning and execution. Example: washing red blood cells using the same protocol as that used for platelets</li> <li>• Failure in monitoring a process or patient status.</li> <li>• Failure in performance of highly developed skills.</li> <li>• Failure in whole body movements. "Slips, trips and falls."</li> </ul> |   |
| <p><b>Patient-related</b></p> <ul style="list-style-type: none"> <li>• Failures related to patient characteristics or conditions which are beyond the control of staff and influence treatment.</li> </ul>  |   |
| <p><b>Other</b></p> <ul style="list-style-type: none"> <li>• Cannot be classified under any of the other categories.</li> </ul>   |   |
| Custom Fields   | Optional. Up to two date fields and ten alphanumeric fields may be added to this form for local use. Each Custom Field must be added to the form in NHSN before it can be selected for use. |
| Comments  | Optional. Enter additional information on the incident  |