United Blood Services
National Office
6210 E. Oak Street / Scottsdale, AZ 85257

Compliance Alert:
Important Information for All Transfusion Services

After recent conversations and visits with several hospital customers, our quality consulting team has noted four recurring compliance issues. Please review the below information to ensure your Transfusion Service is in compliance.

1. The Gel Crossmatch

Recently the following question was posed to CMS: Does the gel crossmatch (which is tested at 37C) fulfill the requirement to demonstrate ABO incompatibility?

The response: The IgG gel card does not fulfill the requirement to demonstrate ABO incompatibility. Therefore, laboratories must use another method, such as electronic crossmatch (if the patient is eligible) or IS (immediate spin) crossmatch, to fulfill this requirement.

First, the labeling clearly indicates that the IgG Gel card is for the direct and indirect antiglobulin tests, i.e., detection of cell-bound IgG antibodies. While the Limitations section of the package insert states that some IgM antibodies may react in the upper portion of the microtube and be trapped in the top portion of the gel card, this limitation should not be interpreted to mean that the card is capable of detecting all IgM antibodies, particularly ABO antibodies.

Second, the IgG Gel card, as well as some other tests on the market, is a low ionic test system. There have been reports that ABO incompatibilities due to IgM antibodies have been/can be missed when the antibodies are weak AND the test is low ionic strength.

2. Use of Fresh Frozen Plasma or FP 24 after 6 hours

The FDA Code of Federal Regulations states that Fresh Frozen Plasma when thawed must be used within 6 hours. To extend the expiration of the Fresh Frozen Plasma for a 24-hour period, both licensed and unlicensed blood establishments **must** submit requests to the Director, Center for Biologics and Research, for an exception to the requirement 21 CFR 606.122.

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Requests for such exceptions or alternative procedures should ordinarily be made in writing. This sample letter for submitting the request can be found on the AABB web site and is available to both members and non-members.

Once you thaw the FFP or FP24, if you relabel it as Thawed Plasma and add a 5-day expiration date, you must remove the license number as it is an unlicensed, unregulated product.

3. FDA Registration

Transfusion services **must** register with the FDA if they:

* routinely collect blood (manual or automated collections)
* routinely do component preparation (e.g., manufacture platelets, FFP, cryo)
* perform pre-storage leukocyte-reduction of blood components in the laboratory
* irradiate blood components
* wash red blood cells
*** combine different components (e.g. red blood cells and plasma to make reconstituted whole blood for neonatal transfusions)**
* freeze or deglycerolize red blood cells
* collect and sell therapeutic exchange plasma
* use the Thermogenesis CryoSeal
* take possession of blood components for purposes of storage, re-labeling, or further processing before distribution
* are not approved for Medicare/Medicaid reimbursement (e.g., VA hospitals or foreign transfusion services)
* manufacture, prepare, or process (including donor testing) any blood products subject to licensure

Transfusion services do **NOT** need to register with FDA if they:
* pool platelets immediately before transfusion
* pool cryo immediately before transfusion
* aliquot or divide components into smaller containers for ease of transfusion
* separate recovered plasma from whole blood to make red blood cells
* collect and discard blood from therapeutic phlebotomies and plasma exchanges
* temporarily store red blood cells from cell savers used in ORs
* issue bedside leukocyte-reduction filters with blood components
* perform compatibility testing and transfuse blood components
* thaw frozen plasma or cryo to prepare for transfusion
* use bed side leukoreduction filters to transfuse non leukoreduced red blood cells.

Refer to the following FDA link for more information, instructions and forms:
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/default.htm

4. Biological Product Deviation Reports

Regardless of licensure or registration status with the FDA, all donor centers, blood banks, and **transfusion services** must report biological product deviations and information relevant to these events to the FDA using form FDA 3486 when the event:

- is associated with manufacturing (i.e. collection, processing, testing, storing, holding, or distributing)
- represents a deviation from cGMP, established specifications or applicable regulations and standards and
- may affect the safety, purity, potency of the product
- occurs when the facility had control of the product and the product has been issued or distributed

Examples of reportable events for a transfusion service include but are not limited to:

- a patient was to receive an irradiated unit but received a non-irradiated unit
- a patient was to receive antigen negative units and did not
- results of compatibility testing were not recorded
- the patient was not eligible for an immediate spin crossmatch and blood was issued based only on an immediate spin crossmatch

5. Proficiency Testing Attestation Statements

Please be aware that if you submit proficiency test results electronically you are still required to maintain an actual signed copy of the attestation statement.

If you use proficiency samples for determining staff competency, submit the proficiency test results prior to having the additional staff perform testing on these samples.

If you have any questions regarding the information provided above or have additional compliance questions, please contact your Center's Technical Director or e-mail our quality consulting team at qualitysource@bloodsystems.org.