

## Backfit Analysis

The NRC has determined that the backfit rule (10 CFR 72.62) does not apply to this direct final rule because this amendment does not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. Therefore, a backfit analysis is not required.

## Congressional Review Act

Under the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

## List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72.

## PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

**Authority:** Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–10 (42 U.S.C. 2014, 2021, 2021b, 2111).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2244 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

■ 2. In § 72.214, Certificate of Compliance 1027 is revised to read as follows:

### § 72.214 List of approved spent fuel storage casks.

\* \* \* \* \*

Certificate Number: 1027.

Initial Certificate Effective Date: May 30, 2000.

Amendment Number 1 Effective Date: October 30, 2007.

SAR Submitted by: Transnuclear, Inc.

SAR Title: Final Safety Analysis

Report for the TN–68 Dry Storage Cask.

Docket Number: 72–1027.

Certificate Expiration Date: May 28, 2020.

Model Number: TN–68.

\* \* \* \* \*

Dated at Rockville, Maryland, this 31st day of July, 2007.

For the Nuclear Regulatory Commission.

**Martin J. Virgilio,**

*Acting Executive Director for Operations.*

[FR Doc. E7–16134 Filed 8–15–07; 8:45 am]

BILLING CODE 7590–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 606, 607, 610, and 640

[Docket No. 2007N–0264]

### Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components and Source Plasma to be more consistent with current practices in the blood industry and to remove

unnecessary or outdated requirements. We are taking this action as part of our continuing effort to reduce the burden of unnecessary regulations on industry and to revise outdated regulations without diminishing public health protection.

Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under our usual procedures for notice and comment in the event that we receive any significant adverse comments on the direct final rule. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

**DATES:** This direct final rule is effective February 19, 2008. Submit written or electronic comments by October 30, 2007. If we receive no significant adverse comments during the specified comment period, we intend to publish a confirmation document on or before the effective date of this direct final rule confirming that the direct final rule will go into effect on February 19, 2008. If we receive any significant adverse comments during the comment period, we intend to withdraw this direct final rule before its effective date by a notice published in the **Federal Register**.

**ADDRESSES:** You may submit comments, identified by Docket No. 2007N–0264, by any of the following methods:  
**Electronic Submissions**  
Submit electronic comments in the following ways:

• Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

• Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.  
**Written Submissions**  
Submit written submissions in the following ways:

• FAX: 301–827–6870.  
• Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under **Electronic Submissions**.

**Instructions:** All submissions received must include the agency name and

Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Stephen M. Ripley, Center for Biologics Evaluation and Research (HF-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Direct Final Rulemaking**

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described its procedures on when and how the agency will employ direct final rulemaking. We have determined that this rule is appropriate for direct final rulemaking because we believe that it is noncontroversial and we anticipate no significant adverse comments. Consistent with our procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule on the same subject matter. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event that the direct final rule is withdrawn because of any significant adverse comment. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments received in response to the companion proposed rule will be considered as comments regarding the direct final rule.

We are providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If we receive any significant adverse comments, we intend to withdraw this direct final rule before its effective date by publication of a notice in the **Federal Register**. A significant adverse comment is defined as a comment that explains why the rule

would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If any significant adverse comments are received during the comment period, FDA will publish, before the effective date of this direct final rule, a document withdrawing the direct final rule. If we withdraw the direct final rule, any comments received will be applied to the proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedures.

If FDA receives no significant adverse comments during the specified comment period, FDA intends to publish a document, before the effective date of the direct final rule, confirming the effective date.

##### **II. Legal Authority**

FDA is issuing this new rule under the biological products and communicable diseases provisions of the Public Health Service Act (PHS Act) (42 U.S.C. 262-264), and the drugs, devices, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 351-353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled, and to prevent the introduction, transmission, and spread of communicable disease.

##### **III. Highlights of the Direct Final Rule**

FDA is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. We are issuing these amendments as a direct final rule because we have concluded that they are noncontroversial and that there is little likelihood that there will be comments opposing the rule. Any comment recommending additional changes to these regulations will not be considered to be a "significant adverse comment" unless the comment demonstrates that the change being made in the direct final rule represents a major departure from current regulations or accepted industry standards, or cannot be implemented without additional amendments to the regulation. Below we identify each of the changes included in this direct final rule.

We are amending 21 CFR 606.3(i) by revising the definition of "processing" to mean any procedure employed after collection and before "or after" compatibility testing of blood. The current regulation states that processing means any procedure employed after collection and before compatibility testing of blood. Because blood components occasionally are further processed after compatibility testing has been performed, we are revising this definition.

We are amending 21 CFR 607.65(f) by removing the words "approved for Medicare reimbursement and" and replacing with the words "that is certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services and which are". As a result of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the implementing regulations adopted by the Centers for Medicare and Medicaid Services (CMS), the inspection regime relied on in a 1983 Memorandum of Understanding (MOU) between FDA and the Health Care Financing Administration (HCFA), now CMS, will be modified. Under the CLIA program, clinical laboratories must be surveyed by CMS (either directly or through a State survey agency), unless they are located in a CLIA-approved State, or are accredited by a CMS-approved accreditation organization. CLIA regulations apply to clinical laboratories regardless of

whether or not the laboratories seek Medicare participation. FDA is amending this regulation to make it consistent with updates in the CMS regulations.

We are amending 21 CFR 610.53(c) by revising the dating period in the table for Platelets, Red Blood Cells Deglycerolized, and Red Blood Cells Frozen. Although the current recommended dating period will remain unchanged for Platelets and Red Blood Cells Deglycerolized, we are adding that a different dating period could apply for these products if so specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluation and Research (CBER). This change will allow for flexible dating periods depending on the type of collecting, processing, and storage system used. In addition, under Red Blood Cells Frozen, we are revising the dating period from 3 years to 10 years, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER. This change will allow for flexible dating periods depending on the type of collecting, processing, and storage system used.

Under § 640.4(h) (21 CFR 640.4(h)), we are revising the temporary storage temperature for blood that is transported from the donor center to the processing laboratory. We are revising the range to between 1 and 10 °C until the blood arrives at the processing laboratory. We are making this revision to be consistent with 21 CFR 600.15 which allows for shipping temperatures of Whole Blood to be from 1 to 10 °C, and for consistency with current industry practice. In addition, we are revising the applicability of this requirement to Whole Blood unless it is to be further processed into another component, such as Platelets or Red Blood Cells Leukocytes Reduced. The current regulation applies only to Whole Blood unless the blood is to be used as a source for Platelets. This change will clarify that processing Whole Blood into other components, in addition to Platelets, is acceptable. For Whole Blood that is to be processed into another component, we are revising this regulation to state that the blood must be stored in an environment maintained at a temperature range that is specified for that component in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER. We are also amending the term donor "clinic" to donor "center" for consistency with § 640.4(b) and current terminology.

We are removing and reserving § 640.21(b) (21 CFR 640.21(b)) because this provision is obsolete, as well as removing the reference to plasmapheresis in 21 CFR 640.20(b). Improvements in technology now allow establishments to collect Platelets by automated methods eliminating the need for the collection of platelets by manual plasmapheresis. Currently, establishments may collect Platelets by automated platelet-specific apheresis collection procedures. We are amending § 640.21(c) by adding that plateletpheresis donors must meet the criteria for suitability as prescribed in 21 CFR 640.3 and 640.63(c)(6), or as described in an approved biologics license application (BLA) or an approved supplement to a BLA, and that informed consent must be obtained as prescribed in 21 CFR 640.61. This revision will clarify that registered facilities must follow the suitability requirements for plateletpheresis donors.

We are removing and reserving § 640.22(b) (21 CFR 640.22(b)) because this regulation is obsolete. As previously mentioned, improvements in technology now allow establishments to collect Platelets by automated methods, eliminating the need for the collection of platelets by manual plasmapheresis. Currently, establishments may collect Platelets by automated platelet-specific apheresis collection procedures. We are amending § 640.22(c) by adding that if plateletpheresis is used, the procedure for collection must be as prescribed in 21 CFR 640.62 - *Medical supervision*; 21 CFR 640.64 - *Collection of blood for Source Plasma*; and 21 CFR 640.65 - *Plasmapheresis*, or as described in an approved BLA or an approved supplement to a BLA. This revision will clarify that registered facilities must follow the collection of source material requirements for plateletpheresis donors.

We are amending 21 CFR 640.24(a) to allow Platelets to be pooled under certain circumstances. That is, Platelets may be pooled if such processing is specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER. We are amending the regulation to provide flexibility depending on the type of collecting, processing, and storage system used.

We are amending 21 CFR 640.25(b)(2) by revising the pH level from "6.0" to "6.2" for consistency with current industry practice. Studies have shown that a lower pH may adversely affect platelet function (Refs. 1 and 2).

We are amending 21 CFR 640.30(a) by revising the term "product," to

"component," for consistency with current terminology of the proper name. We are also adding an alternative definition of Plasma, namely, "The fluid portion of human blood intended for intravenous use which is prepared by apheresis methods as specified in the directions for use for the blood collecting, processing, and storage system including closed and open systems." We are making this change because Plasma is now collected by other methods, such as apheresis collection, in addition to being collected as a byproduct of Whole Blood collection.

We are amending 21 CFR 640.32(a) to add that a different storage temperature may be used for Whole Blood intended for further manufacturing into Plasma, Fresh Frozen Plasma, or Liquid Plasma. Any different storage temperature would be specified in the directions for use for the blood collecting, processing, and storage system. This change will allow for flexible storage temperatures depending on the particular type of system used.

We are amending 21 CFR 640.34(b) by adding the phrase "or collected by an apheresis procedure" in the second sentence to clarify that this section also applies to plasma collected by apheresis procedures. We require that fresh frozen plasma using the apheresis procedure also be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to, and minimal manipulation of, the donor's tissue.

We are amending § 640.64(b) (21 CFR 640.64(b)) by removing the second sentence that states, "The amount of anticoagulant required for the quantity of blood to be collected shall be in the blood container when it is sterilized." This sentence is being removed because of technological advances. Now, the anticoagulant does not always have to be in the collection set. The anticoagulant can be connected by a "sterile docking" procedure or attached separately, as is the case with automated apheresis collection. We are also amending § 640.64(c) by removing the specific anticoagulant solution formulas and indicating that the anticoagulant solutions must be compounded and used according to a formula approved by the Director, CBER. We have determined that it is unnecessary to provide specific formulae for anticoagulant solutions in the regulations, and that manufacturers should be able to use any anticoagulant approved by FDA for such use by the manufacturer.

We have also revised the previous regulations, where applicable, by using "must" or "is" instead of "shall",

depending on the circumstances. We have made these revisions for plain language purposes. These editorial changes are for clarity only and do not change the substance of the requirements. We will continue to make these changes in other applicable regulations as they are revised in future rulemakings. In addition, we will continue to make the change from "product" to "component" in other applicable regulations as they are revised in future rulemakings.

#### IV. Analysis of Impacts

##### *A. Review Under Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Act of 1995*

FDA has examined the impacts of the direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the direct final rule amendments have no compliance costs and do not result in any new requirements, the agency certifies that the direct final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this direct final rule to result in any 1-year expenditure that would meet or exceed this amount.

##### *B. Environmental Impact*

The agency has determined, under 21 CFR 25.31(h), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

##### *C. Federalism*

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the direct final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the direct final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### V. Paperwork Reduction Act of 1995

This direct final rule contains no collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

#### VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### VII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Scott Murphy, "Platelet Storage for Transfusion," *Seminars in Hematology*, 22(3): 165–177, July 1985.
2. L. Dumont and T. VandenBroeke, "Seven-Day Storage of Apheresis Platelets Report of an In Vitro Study," 43: 143–150, *Transfusion*, February 2003.

#### List of Subjects

##### *21 CFR Part 606*

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

##### *21 CFR Part 607*

Blood.

##### *21 CFR Part 610*

Biologics, Labeling, Reporting and recordkeeping requirements.

##### *21 CFR Part 640*

Blood, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated by the Commissioner of Food and Drugs, 21 CFR parts 606, 607, 610, and 640 are amended as follows:

#### **PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS**

■ 1. The authority citation for 21 CFR part 606 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 2. Section 606.3 is amended by revising paragraph (i) to read as follows:

##### **§ 606.3 Definitions.**

\* \* \* \* \*

(i) *Processing* means any procedure employed after collection, and before or after compatibility testing of blood, and includes the identification of a unit of donor blood, the preparation of components from such unit of donor blood, serological testing, labeling and associated recordkeeping.

\* \* \* \* \*

#### **PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS**

■ 3. The authority citation for 21 CFR part 607 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

■ 4. Section 607.65 is amended by revising the first sentence in paragraph (f) to read as follows:

##### **§ 607.65 Exemptions for blood product establishments.**

\* \* \* \* \*

(f) Transfusion services which are a part of a facility that is certified under the Clinical Laboratory Improvement

Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services and which are engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collect nor process blood and blood components. \* \* \*

## PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 5. The authority citation for 21 CFR part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 6. Section 610.53 is amended in paragraph (c) in the table by revising the entries for Platelets, Red Blood Cells Deglycerolized, and Red Blood Cells Frozen to read as follows:

### § 610.53 Dating periods for licensed biological products.

\* \* \* \* \*

(c) \* \* \*

A	B	C	D
Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated).	Manufacturer's storage period 0 °C or colder (unless otherwise stated).	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
*	*	*	*
Platelets	Not applicable .....	do .....	72 hours from time of collection of source blood, provided labeling recommends storage at 20 to 24°C or between 1 and 6°C, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluation and Research (CBER).
*	*	*	*
Red Blood Cells Deglycerolized	do .....	do .....	24 hours after removal from storage at 65°C or colder, provided labeling recommends storage between 1 and 6°C, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER.
Red Blood Cells Frozen	do .....	do .....	10 years from date of collection of source blood, provided labeling recommends storage at 65°C or colder, or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER.

\* \* \* \* \*

## PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

■ 7. The authority citation for 21 CFR part 640 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 8. Section 640.4 is amended by revising paragraph (h) to read as follows:

### § 640.4 Collection of the blood.

\* \* \* \* \*

(h) *Storage.* Whole Blood must be placed in storage at a temperature between 1 and 6°C immediately after collection unless the blood is to be further processed into another component or the blood must be transported from the donor center to the processing laboratory. If transported, the blood must be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously at a temperature range between 1 and 10°C until arrival at the processing laboratory. At the processing laboratory,

the blood must be stored at a temperature between 1 and 6°C. Blood from which a component is to be prepared must be held in an environment maintained at a temperature range specified for that component in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, CBER.

■ 9. Section 640.20 is amended by revising paragraph (b) to read as follows:

### § 640.20 Platelets.

\* \* \* \* \*

(b) *Source.* The source material for Platelets is plasma which may be obtained by whole blood collection or by plateletpheresis.

■ 10. Section 640.21 is amended by removing and reserving paragraph (b) and revising paragraph (c) to read as follows:

### § 640.21 Suitability of donors.

\* \* \* \* \*

(b) [Reserved]

(c) Plateletpheresis donors must meet the criteria for suitability as prescribed in §§ 640.3 and 640.63(c)(6) or as described in an approved biologics

license application (BLA) or an approved supplement to a BLA. Informed consent must be obtained as prescribed in § 640.61.

■ 11. Section 640.22 is amended by removing and reserving paragraph (b) and revising paragraph (c) to read as follows:

### § 640.22 Collection of source material.

\* \* \* \* \*

(b) [Reserved]

(c) If plateletpheresis is used, the procedure for collection must be as prescribed in §§ 640.62, 640.64 (except paragraph (c)), and 640.65, or as described in an approved biologics license application (BLA) or an approved supplement to a BLA.

\* \* \* \* \*

■ 12. Section 640.24 is amended by revising paragraph (a) to read as follows:

### § 640.24 Processing.

(a) Separation of plasma and platelets and resuspension of the platelets must be in a closed system. Platelets must not be pooled during processing unless the platelets are pooled as specified in the directions for use for the blood collecting, processing, and storage

system approved for such use by the Director, Center for Biologics Evaluation and Research.

\* \* \* \*

#### § 640.25 [Amended]

■ 13. Section 640.25 is amended in paragraph (b)(2) by removing “6.0” and adding in its place “6.2”.

■ 14. Section 640.30 is amended by revising paragraph (a) to read as follows:

#### § 640.30 Plasma.

(a) *Proper name and definition.* The proper name of this component is Plasma. The component is defined as:

(1) The fluid portion of one unit of human blood intended for intravenous use which is collected in a closed system, stabilized against clotting, and separated from the red cells; or

(2) The fluid portion of human blood intended for intravenous use which is prepared by apheresis methods as specified in the directions for use for the blood collecting, processing, and storage system including closed and open systems.

\* \* \* \*

■ 15. Section 640.32 is amended by revising paragraph (a) to read as follows:

#### § 640.32 Collection of source material.

(a) Whole Blood must be collected, transported, and stored as prescribed in § 640.4. When whole blood is intended for Plasma, Fresh Frozen Plasma, and Liquid Plasma, until the plasma is removed, the whole blood must be maintained at a temperature between 1 and 6 °C or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluations and Research. Whole blood intended for Platelet Rich Plasma must be maintained as prescribed in § 640.24 until the plasma is removed. The red blood cells must be placed in storage at a temperature between 1 and 6 °C immediately after the plasma is separated.

\* \* \* \*

■ 16. Section 640.34 is amended by revising the second sentence in paragraph (b) to read as follows:

#### § 640.34 Processing.

\* \* \* \*

(b) *Fresh Frozen Plasma.* \* \* \* The plasma must be separated from the red blood cells or collected by an apheresis procedure, and placed in a freezer within 8 hours or within the timeframe specified in the directions for use for the

blood collecting, processing, and storage system, and stored at -18 °C or colder.

\* \* \* \*

■ 17. Section 640.64 is amended by revising paragraphs (b) and (c) to read as follows:

#### § 640.64 Collection of blood for source plasma.

\* \* \* \*

(b) *Blood containers.* Blood containers and donor sets must be pyrogen-free, sterile, and identified by lot number.

(c) *The anticoagulant solution.* The anticoagulant solution must be sterile and pyrogen-free. Anticoagulant solutions must be compounded and used according to a formula that has been approved for the applicant by the Director, Center for Biologics Evaluation and Research.

\* \* \* \*

Dated: July 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-15943 Filed 8-15-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF STATE

### 22 CFR Parts 22 and 51

[Public Notice: 5888]

RIN 1400-AC39

### Passport Procedures—Amendment to Expedited Passport Processing Regulation

AGENCY: Department of State.

ACTION: Interim final rule.

**SUMMARY:** This interim final rule changes the definition of “expedited passport processing” from the 3-business day period to a number of business days as may be published from time to time on the Department’s Web site, <http://www.travel.state.gov>. This change is meant to ensure that the Department can continue to offer this service consistent with its regulations, despite increases in demand for it. It is also meant to ensure that the public can easily determine the current standards for expedited passport processing. Further, this interim final rule makes a conforming amendment to the Schedule of Fees for Consular Services.

**DATES:** *Effective date:* This interim final rule becomes effective August 16, 2007.

*Comment date:* The Department of State will accept written comments from interested persons up to October 15, 2007.

**ADDRESSES:** Interested parties may submit comments at any time by any of the following methods:

- *Mail (paper, disk, or CD-ROM submissions):* Comments by mail are to be addressed to the Office of Legal Affairs and Law Enforcement, U.S. Department of State, 2100 Pennsylvania Ave., NW., Suite 300, Washington, DC 20037.

- *Internet:* Comments by Internet are to be sent to <http://www.regulations.gov>. This notice can also be viewed from this Internet address.

- *Electronically:* You may submit electronic comments to [ExpediteRuleComments@state.gov](mailto:ExpediteRuleComments@state.gov). You must include the RIN in the subject line of your message. Attachments must be in Microsoft Word.

*Instructions:* All submissions must include the agency name and docket number. All comments will be posted without change to <http://www.regulations.gov>, including any personal information sent with each comment.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information regarding this regulatory amendment should be directed to Susan M. Bozinko, Bureau of Consular Affairs, Passport Services, Division of Legal Affairs, U.S. Department of State, Washington, DC 20037, who may be reached at 202-663-2491 or e-mailed at [BozinkoSM@state.gov](mailto:BozinkoSM@state.gov).

**SUPPLEMENTARY INFORMATION:** Section 7209 of the Intelligence Reform and Terrorism Prevention Act (IRTPA), enacted on December 17, 2004, requires the Secretary of Homeland Security, in consultation with the Secretary of State, to develop expeditiously a plan to require most U.S. citizens and certain other categories of individuals to present a passport or other documentation of identity and citizenship deemed sufficient by the Secretary of Homeland Security when entering the United States.

The Department of State’s Office of Passport Services (Passport Services) began planning for increased passport demand even before Congress passed IRTPA. It planned for a sharp increase in passport applications and anticipated the need for increased staff to handle the demand. Recognizing the uncertainty of passport demand and the need for reliable information to guide its planning efforts, Passport Services contracted for a passport demand study in 2005, and used the data from this study to initiate a program of resource upgrades for meeting demand.

Beginning in February 2007, it became apparent that passport demand