

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. E7-15942 Filed 8-15-07; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Parts 53 and 301**

[REG-142039-06; REG-139268-06]

**RIN 1545-BG18; 1545-BG20**

**Excise Taxes on Prohibited Tax Shelter Transactions and Related Disclosure Requirements; Disclosure Requirements With Respect to Prohibited Tax Shelter Transactions; Requirement of Return and Time for Filing; Correction**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Corrections to notice of proposed rulemaking by cross-reference to temporary regulations and notice of proposed rulemaking.

**SUMMARY:** This document contains corrections to notice of proposed rulemaking by cross-reference to temporary regulations (REG-142039-06) and notice of proposed rulemaking (REG-139268-06) that were published in the **Federal Register** on Friday, July 6, 2007 (72 FR 36927) providing guidance under 4965 of the Internal Revenue Code and relating to entity-level and manager-level excise taxes with respect to prohibited tax shelter transactions to which tax-exempt entities are parties; §§ 6033(a)(2) and 6011(g), relating to certain disclosure obligations with respect to such transactions; and §§ 6011 and 6071, relating to the requirement of a return and time for filing with respect to section 4965 taxes.

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations, Galina Kolomietz, (202) 622-6070, or Michael Blumenfeld, (202) 622-1124 (not toll-free numbers). For questions specifically relating to qualified pension plans, individual retirement accounts, and similar tax-favored savings arrangements, contact Dana Barry, (202) 622-6060 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:****Background**

The notice of proposed rulemaking by cross-reference to temporary regulations and notice of proposed rulemaking that are the subjects of this correction are under sections 6011, 6033, 6071, and 4965 of the Internal Revenue Code.

**Need for Correction**

As published, proposed regulations (REG-142039-06 and REG-139268-06) contain errors that may prove to be misleading and are in need of clarification.

**Correction of Publication**

Accordingly, the publication of the proposed regulations (REG-142039-06 and REG-139268-06) which were the subjects of FR Doc.E7-12902), is corrected as follows:

**§ 53.4965-4 [Corrected]**

1. On page 36933, column 1, § 53.4365-4(c) *Example 2.*, line 12 of the paragraph, the language “by Notice 2006-16 (2006-9 IRB 538). The” is corrected to read “by Notice 2006-16 (2006-9 IRB 538)). The”.

**§ 53.4965-8 [Corrected]**

2. On page 36936, column 3, § 53.4965-8(e), line 2 of the paragraph, the language “*periods.* If a transaction (other than a” is corrected to read “*periods.* If a transaction other than a”.

**PART 301—PROCEDURE AND ADMINISTRATION**

3. On page 36938, column 1, paragraph 8, line 2, the language “301 continues to read, part, as follows:” is corrected to read “301 continues to read, in part, as follows:”.

**§ 301.6011(g)-1 [Corrected]**

4. On page 36938, column 1, § 301.6011(g)-1(a)(2)(i), line 4 of the paragraph, the language “of its tax-exempt, tax-indifferent or tax-” is corrected to read “of its tax-exempt, tax indifferent or tax-”.

5. On page 36938, column 1, § 301.6011(g)-1(a)(2)(ii), line 3 of the paragraph, the language “exempt, tax-indifferent or tax-favored” is corrected to read “exempt, tax indifferent or tax-favored”.

**§ 301.6033-5 [Corrected]**

6. On page 36939, column 1, § 301.6033-5, line 1 of the paragraph, the language “[The text of this section is the same” is corrected to read “[The

text of the proposed amendment to § 301.6033-5 is the same”.

**LaNita Van Dyke,**

*Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).*

[FR Doc. E7-16080 Filed 8-15-07; 8:45 am]

**BILLING CODE 4830-01-P**

**DEPARTMENT OF AGRICULTURE****Forest Service****36 CFR Part 220****RIN 0596-AC49****National Environmental Policy Act Procedures**

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of proposed rule; request for comment.

**SUMMARY:** The Forest Service is proposing to move its National Environmental Policy Act (NEPA) implementing procedures from Forest Service Manual (FSM) 1950 and Forest Service Handbook (FSH) 1909.15 to 36 Code of Federal Regulations, part 220 (36 CFR 220). The Agency also proposes to clarify existing NEPA procedures and add new procedures to incorporate Council on Environmental Quality (CEQ) guidance and to better align Agency NEPA procedures with Agency decision processes.

Agency explanatory guidance interpreting CEQ and Agency procedures in regulation will remain in FSH 1909.15. Agency NEPA authority, objectives, policy, and responsibilities will remain in FSM 1950.

This rule would meet 40 CFR 1507.3 by placing Agency-implementing procedures in their proper regulatory position. Maintaining Agency explanatory guidance in directives would facilitate timely Agency responses to new ideas, new information, procedural interpretations, training needs, and editorial changes to assist field units when implementing the NEPA process. Finally, the proposed changes to the Forest Service NEPA procedures are intended to provide an environmental analysis process that fits better with modern thinking on decisionmaking, collaboration, and adaptive management to meet the intent of NEPA through establishing incremental alternative development, and adaptive management principles.

**DATES:** Comments must be received in writing by October 15, 2007.

**ADDRESSES:** Comments concerning this notice should be sent by e-mail to

*fsnepa@contentanalysisgroup.com*, or by facsimile to 801-397-2601, or via the U.S. Postal Service to: NEPA Implementation Procedures, C/O Content Analysis Group, 1584 South 500 West, Suite 201, Woods Cross, UT 84010. Electronic or facsimile comments are preferred. If comments are sent via U.S. Postal Service, please do not submit duplicate electronic or facsimile comments. Please confine comments to the proposed move of existing NEPA procedures from FSH to regulation, proposed changes to existing NEPA procedures, and proposed new NEPA procedures and explain the reasons for any recommended changes.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying.

**FOR FURTHER INFORMATION CONTACT:** Joe Carbone, Ecosystem Management Staff, (202) 205-0884, Forest Service, USDA. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m. Eastern Standard Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:****Background and Need for the Proposed Rule**

Council on Environmental Quality (CEQ) regulations at 40 CFR 1507.3 require Federal agencies to adopt procedures as necessary to supplement CEQ's regulations implementing the National Environmental Policy Act (NEPA) and to consult with CEQ during their development and prior to publication in the **Federal Register**. The regulation further encourages agencies to publish agency explanatory guidance for CEQ's regulations and agency procedures.

In 1979, the Forest Service chose to combine its implementing procedures and explanatory guidance in Agency directives (Forest Service Manual 1950 and Forest Service Handbook 1909.15). The blending of NEPA implementing procedures with explanatory guidance requires the Forest Service to provide for public notice and comment and to consult with CEQ, as required by 40 CFR 1507.3, when amending any guidance for explaining CEQ or Agency procedures, resulting in an increased administrative burden for the Agency and CEQ.

This proposal would meet the intent of 40 CFR 1507.3 by placing Agency-implementing procedures in their proper regulatory position. Placing Agency explanatory guidance in directives would facilitate quicker