

donor at the time of collecting the unit of blood, and these tests shall include the following:

\* \* \* \* \*

(c) *Determination of the Rh factors.* Each container of Whole Blood shall be classified as to Rh type on the basis of tests done on the sample. The label shall indicate the extent of typing and the results of all tests performed. If the test, using Anti-D Blood Grouping Reagent, is positive, the container may be labeled "Rh Positive." If the test is negative, the results shall be confirmed by further testing which shall include tests for the "weak D (formerly D<sup>u</sup>)." Blood may be labeled "Rh Negative" if further testing is negative. Units testing positive after additional more specific testing shall be labeled as "Rh Positive." Only Anti-Rh Blood Grouping Reagents licensed under, or that otherwise meet the requirements of, this subchapter shall be used, and the technique used shall be that for which the reagent is specifically designed to be effective.

\* \* \* \* \*

9. Section 640.15 is revised to read as follows:

**§ 640.15 Segments for testing.**

Segments collected in integral tubing shall meet the following standards:

(a) One or more segments shall be provided with each unit of Whole Blood or Red Blood Cells when issued or reissued.

(b) Before they are filled, all segments shall be marked or identified so as to relate them to the donor of that unit of red cells.

(c) All segments accompanying a unit of Red Blood Cells shall be filled at the time the blood is collected or at the time the final product is prepared.

10. Section 640.16 is amended by revising paragraph (a) to read as follows:

**§ 640.16 Processing.**

(a) *Separation.* Within the timeframe specified in the directions for use for the blood collecting, processing, and storage system used, Red Blood Cells may be prepared either by centrifugation, done in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation. A portion of the plasma sufficient to insure optimal cell preservation shall be left with the red cells except when a cryoprotective substance or additive solution is added for prolonged storage.

\* \* \* \* \*

11. Section 640.24 is amended by revising paragraph (b) to read as follows:

**§ 640.24 Processing.**

\* \* \* \* \*

(b) Immediately after collection, the whole blood or plasma shall be held in storage between 20 and 24 °C unless it must be transported from the collection center to the processing laboratory. During such transport, all reasonable methods shall be used to maintain the temperature as close as possible to a range between 20 and 24 °C until it arrives at the processing laboratory where it shall be held between 20 and 24 °C until the platelets are separated. The platelet concentrate shall be separated within 4 hours or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.

\* \* \* \* \*

12. Section 640.34 is amended by revising paragraphs (a) through (d) and (e)(1) to read as follows:

**§ 640.34 Processing.**

(a) *Plasma.* Plasma shall be separated from the red blood cells and shall be stored at -18 °C or colder within 6 hours after transfer to the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system unless the product is to be stored as Liquid Plasma.

(b) *Fresh Frozen Plasma.* Fresh frozen plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma shall be separated from the red blood cells, 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.

(c) *Liquid Plasma.* Liquid Plasma shall be separated from the red blood cells and shall be stored at a temperature of 1 to 6 °C within 4 hours after filling the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.

(d) *Platelet Rich Plasma.* Platelet rich plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and manipulation of the donor's tissue. The plasma shall be separated from the red blood cells by centrifugation within 4 hours after completion of the phlebotomy or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system. The time and speed of the centrifugation shall have been shown to produce a product with at least 250,000 platelets per microliter. The plasma shall be stored at a temperature between 20 and 24 °C immediately after filling

the final container. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20 to 24 °C.

(e) \* \* \*

(1) Platelets shall be separated as prescribed in subpart C of part 640, prior to freezing the plasma. The remaining plasma may be labeled as "Fresh Frozen Plasma," if frozen within 6 hours after filling the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system.

\* \* \* \* \*

13. Section 640.54 is amended by revising paragraph (a)(2) to read as follows:

**§ 640.54 Processing.**

(a) \* \* \*

(2) The plasma shall be placed in a freezer within 8 hours after blood collection or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system. A combination of dry ice and organic solvent may be used for freezing: *Provided*, That the procedure has been shown not to cause the solvent to penetrate the container or leach plasticizer from the container into the plasma.

\* \* \* \* \*

14. Section 640.63 is amended by revising paragraph (c)(11) to read as follows:

**§ 640.63 Suitability of donor.**

\* \* \* \* \*

(c) \* \* \*

(11) Freedom from a history of viral hepatitis after the 11th birthday;

\* \* \* \* \*

Dated: June 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-19461 Filed 8-3-01; 8:45 am]

BILLING CODE 4160-01-S

**POSTAL SERVICE**

**39 CFR Part 266**

**Privacy Act of 1974; Implementation**

**AGENCY:** Postal Service.

**ACTION:** Final rule.

**SUMMARY:** The Postal Service is amending its regulations implementing the Privacy Act of 1974, 5 U.S.C. 552a. This amendment modifies existing regulations (39 CFR 266.9) to exempt system of records, Office of Inspector

General-Investigative File System, USPS 300.010, from certain provisions of the Act and corresponding agency regulations.

**DATES:** This rule is effective on August 6, 2001.

**FOR FURTHER INFORMATION CONTACT:** Howard Cox, Acting Legal Director, Office of Inspector General (703) 248-2164.

**SUPPLEMENTARY INFORMATION:** The Postal Service published a proposed rule on December 27, 2000, to amend 39 CFR 266.9 to apply certain Privacy Act exemptions to the OIG Investigative File System. The Office of Inspector General (OIG) is a component of the Postal Service that performs as one of its principal functions investigations into violations of criminal law in connection with Postal Service programs and operations, pursuant to the Inspector General Act of 1978, as amended. 5 U.S.C. App.3. The OIG Investigative File System falls within the scope of subsections (j)(2), (k)(2), and (k)(5) of the Act. Comments on the proposed rule were due on or before January 26, 2001. We did not receive any comments. Therefore, the rule is adopted as final without any changes.

The Postal Service has exempted certain systems of records that it maintains from specific provisions of the Privacy Act. At the time it adopted the exemptions contained in its Privacy Act regulations (39 CFR 266.9), the Postal Service stated its reason for each exemption in the preamble of the notice of proposed rulemaking (40 FR 37227, August 26, 1975). These reasons were added to the text of § 266.9 by final rule published July 13, 1994 (59 FR 35625). This proposed rule does not change the current application of exemptions, except to apply certain exemptions to the OIG Investigative File System.

**List of Subjects in 39 CFR Part 266**

Privacy.

**PART 266—[AMENDED]**

Accordingly, 39 CFR is amended as set forth below:

1. The authority citation for part 266 continues to read as follows:

**Authority:** 39 U.S.C. 401; 5 U.S.C. 552a.

2. In § 266.9 revise paragraphs (b)(1)(vii), (b)(2) introductory text, (b)(2)(i), (b)(2)(ii), (b)(2)(iii) and add paragraph (b)(2)(viii) to read as follows:

**§ 266.9 Exemptions.**

\* \* \* \* \*

- (b) \* \* \*
- (1) \* \* \*

(vii) Subsection (e)(4)(G) and (H) requires an agency to publish a **Federal Register** notice of its procedures whereby an individual can be notified upon request whether the system of records contains information about the individual, how to gain access to any record about the individual contained in the system, and how to contest its content. Subsection (e)(4)(I) requires the foregoing notice to include the categories of sources in the system.

\* \* \* \* \*

(2) Inspection Requirements—Investigative File System, USPS 080.010, Inspection Requirements—Mail Cover Program, USPS 080.020, and Office of Inspector General-Investigative File System, USPS 300.010. These systems of records are exempt from 5 U.S.C. 552a (c)(3) and (4), (d)(1)–(4), (e)(1)–(3), (e)(4) (G) and (H), (e)(5) and (8), (f), (g), and (m). In addition, system 300.010 is exempt from 5 U.S.C. 552a(e)(4)(I). The reasons for exemption follow:

(i) Disclosure to the record subject pursuant to subsections (c)(3), (c)(4), or (d)(1)–(4) could:

(A) Alert subjects that they are targets of an investigation or mail cover by the Postal Inspection Service or an investigation by the Office of Inspector General;

(B) Alert subjects of the nature and scope of the investigation and of evidence obtained;

(C) Enable the subject of an investigation to avoid detection or apprehension;

(D) Subject confidential sources, witnesses, and law enforcement personnel to harassment or intimidation if their identities were released to the target of an investigation;

(E) Constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation;

(F) Intimidate potential witnesses and cause them to be reluctant to offer information;

(G) Lead to the improper influencing of witnesses, the destruction or alteration of evidence yet to be discovered, the fabrication of testimony, or the compromising of classified material; and

(H) Seriously impede or compromise law enforcement, mail cover, or background investigations that might involve law enforcement aspects as a result of the above. (ii) Application of subsections (e)(1) and (e)(5) is impractical because the relevance, necessity, or correctness of specific information might be established only after considerable analysis and as the

investigation progresses. As to relevance (subsection (1)), effective law enforcement requires the keeping of information not relevant to a specific Postal Inspection Service investigation or Office of Inspector General investigation. Such information may be kept to provide leads for appropriate law enforcement and to establish patterns of activity that might relate to the jurisdiction of the Office of Inspector General, Postal Inspection Service, and/or other agencies. As to accuracy (subsection (e)(5)), the correctness of records sometimes can be established only in a court of law.

(iii) Application of subsections (e)(2) and (3) would require collection of information directly from the subject of a potential or ongoing investigation. The subject would be put on alert that he or she is a target of an investigation by the Office of Inspector General, or an investigation or mail cover by the Postal Inspection Service, enabling avoidance of detection or apprehension, thereby seriously compromising law enforcement, mail cover, or background investigations involving law enforcement aspects. Moreover, in certain circumstances the subject of an investigation is not required to provide information to investigators, and information must be collected from other sources.

\* \* \* \* \*

(viii) The requirement of subsection (e)(4)(I) does not apply to system 300.010, because identification of record source categories could enable the subject of an investigation to improperly interfere with the conduct of the investigation.

\* \* \* \* \*

**Stanley F. Mires,**

*Chief Counsel, Legislative.*

[FR Doc. 01-19474 Filed 8-3-01; 8:45 am]

**BILLING CODE 7710-12-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[PA-4105a; FRL-7021-6]

**Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; VOC and NO<sub>x</sub> RACT Determinations for Twenty-Five Individual Sources**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve revisions to the