

Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use – Compliance Policy

Guidance for Industry

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the agency has determined that prior public participation is not feasible or appropriate.

FDA invites comments on this guidance. Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*. FDA will review any comments we receive and revise the guidance when appropriate.

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

**U.S. Department of Health and Human Services
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Contains Nonbinding Recommendations

Table of Contents

I. INTRODUCTION..... 1

II. BACKGROUND 2

**III. AUTOLOGOUS DONOR ELIGIBILITY REQUIREMENTS - COMPLIANCE
POLICY 2**

A. General Donor Eligibility Requirements (21 CFR 630.10) 2

**B. Donor Eligibility Requirements Specific to Whole Blood, Red Blood Cells
and Plasma Collected by Apheresis (21 CFR 630.15)..... 3**

C. Exceptions for Certain Ineligible Donors (21 CFR 630.20) 4

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance addresses the regulatory requirements for determining donor eligibility that apply to establishments that collect blood and blood components (blood establishments) intended solely for autologous use. On May 22, 2015, in order to better assure the safety of the nation's blood supply and to help protect donor health, FDA finalized its revision of the applicable requirements for blood establishments to test donors for infectious disease, and to determine that donors are eligible to donate and that donations are suitable for transfusion or further manufacture (Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use, 80 FR 29842 (donor eligibility rule)¹). The donor eligibility rule includes requirements related to current good manufacturing practice, donation testing, donor eligibility, and donation suitability (in 21 CFR Parts 606, 610, 630, and 640). It became effective on May 23, 2016.²

FDA has developed this guidance in response to questions from blood establishments concerning the applicability of the donor eligibility rule to autologous donations. The guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain donor eligibility determination requirements in collecting blood and blood components intended solely for autologous use.

In general, FDA's guidance documents, including this guidance document, do not establish legally-enforceable responsibilities. Instead, guidance documents describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidance documents means that something is suggested or recommended, but not required.

¹ <https://www.gpo.gov/fdsys/pkg/FR-2015-05-22/html/2015-12228.htm>.

² Unless otherwise specified, all regulation citations refer to the requirements in the donor eligibility rule that became effective May 23, 2016.

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II. BACKGROUND

A small proportion of collections of blood and blood components are intended for autologous use. In those instances, the autologous donor presents with a physician's prescription for the collection of the donor's blood for the donor's own upcoming medical (e.g., surgical) procedure. If the donor ultimately does not need the blood, blood establishments may, in some instances, use these donations for allogeneic (i.e., intended for transfusion to a recipient other than the donor) transfusions. This is referred to as "cross-over."

Blood establishments have requested clarification on certain requirements of the donor eligibility rule and the applicability of certain sections of the donor eligibility rule to the collection of blood and blood components intended for autologous use. To address these questions, FDA has developed this guidance to clarify the Agency's policy with respect to the requirements for autologous donors of blood and blood components intended solely for autologous use, (i.e., not subject to cross-over). Specifically:

- Section III.A describes FDA's policy with respect to requirements in 21 CFR 630.10 relating to screening autologous donors for relevant transfusion-transmitted infections (RTTI);
- Section III.B describes FDA's policy with respect to the requirement in 21 CFR 630.15(a)(1)(ii) that the responsible physician examine the autologous donor to permit more frequent collections; and,
- Section III.C describes FDA's policy with respect to the requirement in 21 CFR 630.20(a) that the responsible physician determine and document that the autologous donor's health permits the collection of blood and blood components.

III. AUTOLOGOUS DONOR ELIGIBILITY REQUIREMENTS - COMPLIANCE POLICY

A. General Donor Eligibility Requirements (21 CFR 630.10)

Autologous donors have long been permitted to donate blood for their own use even if they do not meet certain donor eligibility criteria that apply to allogeneic donors because autologous donors are not exposed to new transfusion-transmitted infections in receiving their own blood. For example, FDA does not require testing of autologous donations for relevant transfusion-transmitted infections (RTTI, see 21 CFR 630.3(h)) unless the donations are used for allogeneic transfusion or shipped to another establishment (21 CFR 610.40(d)). Consistent with this approach to testing of autologous donations, FDA does not believe it is necessary to assess autologous donors for risks for RTTI as required in 21 CFR 630.10, provided that the donation is intended solely for autologous use.

Accordingly, provided that: 1) the collection of blood and blood components is intended solely for autologous use (i.e., the blood or blood components are not subject to cross-over), and 2) the blood establishment meets all other applicable requirements in

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21 CFR Parts 606, 610, 630, and 640, FDA does not intend to take regulatory action regarding violations of:

1. 21 CFR 630.10(b), with respect to providing donors of blood and blood components educational material;
2. 21 CFR 630.10(d)(1), with respect to consulting the records of deferred donors of blood and blood components;
3. 21 CFR 630.10(e)(1), with respect to assessing a donor of blood and blood components for an increased risk for, or evidence of, an RTTI;
4. 21 CFR 630.10(e)(2)(iii), with respect to assessing a donor of blood and blood components for travel to, or residence in, an area endemic for transfusion-transmitted infection; and
5. 21 CFR 630.10(e)(2)(vii), with respect to assessing whether the donor of blood and blood components is a recipient of a xenotransplantation product.

Licensed blood establishments must report changes to their standard operating procedures (SOPs) as Changes Being Effectuated (CBE) supplements under 21 CFR 601.12(c)(5). See 21 CFR 601.12(a)(3).

B. Donor Eligibility Requirements Specific to Whole Blood, Red Blood Cells and Plasma Collected by Apheresis (21 CFR 630.15)

Section 630.15(a)(1)(i) addresses donation frequency for Whole Blood or Red Blood Cells. Section 630.15(a)(1)(ii) provides an exception to the donation frequency requirement provided that:

1. The donation is for autologous use as prescribed by the donor's physician; and
2. The responsible physician of the blood establishment examines the donor at the time of donation, determines the donation may proceed, and documents this determination.

With regard to the second condition above, in light of the medical oversight provided by the autologous donor's physician, FDA believes blood establishments can appropriately protect autologous donors' health by following SOPs that are approved by the responsible physician of the blood establishment and that define criteria for when the autologous donation may proceed and the conditions under which the responsible physician must be consulted.

Accordingly, for autologous donors of blood and blood components intended solely for autologous use, we do not intend to take regulatory action with respect to the requirement in 21 CFR 630.15(a)(1)(ii) that the responsible physician examine the donor and determine and document that the donation may proceed, and the corresponding requirement in 21 CFR 630.5(b)(1)(i)(A) that the responsible physician not delegate the examination of the autologous donor and the determination of the autologous donor's

Contains Nonbinding Recommendations

health, provided that the blood establishment develops and follows appropriate SOPs³ that:

- are approved by the responsible physician of the blood establishment;
- provide instructions on how staff should determine that an autologous donor of blood and blood components has been referred by his or her physician and presents with a prescription to undergo an autologous donation;
- define criteria for autologous collections of blood and blood components to proceed; *and* that
- describe the conditions under which the responsible physician must be consulted to determine and document that an autologous donor's health permits the collection of blood and blood components. (The SOPs may clarify that the responsible physician may make this determination by telephonic or other offsite consultation).

C. Exceptions for Certain Ineligible Donors (21 CFR 630.20)

Section 630.20(a) permits blood establishments to collect blood and blood components from an otherwise ineligible autologous donor provided certain conditions are met:

1. The donation is for autologous use only, as prescribed by the donor's physician;
2. The donor has a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood or a hematocrit value no less than 33 percent; and
3. The responsible physician of the blood establishment determines and documents the donor's health permits the collection procedure.

With respect to the third condition above, in light of the medical oversight provided by the autologous donor's physician, FDA believes blood establishments can appropriately protect autologous donors' health by following SOPs that are approved by the responsible physician of the blood establishment and that define criteria for when the autologous donation may proceed and the conditions under which the responsible physician must be consulted.

Accordingly, for autologous donors of blood and blood components intended solely for autologous use, we do not intend to take regulatory action with respect to the requirement in 21 CFR 630.20(a) that the responsible physician determines and documents that the donor's health permits the collection procedure, or the corresponding requirement in 21 CFR 630.5(b)(1)(i)(B) that the responsible physician not delegate the determination of the autologous donor's health, provided that the blood establishment develops and follows appropriate SOPs⁴ that:

³Licensed blood establishments must report such changes to their SOPs as CBE supplements under 21 CFR 601.12(c)(5). See 21 CFR 601.12(a)(3).

⁴*Id.*

Contains Nonbinding Recommendations

- are approved by the responsible physician of the blood establishment;
- provide instructions on how staff should determine that an autologous donor of blood and blood components has been referred by his or her physician and presents with a prescription to undergo an autologous donation;
- define criteria for autologous collections of blood and blood components to proceed' *and* that
- describe the conditions under which the responsible physician must be consulted to determine and document that an autologous donor's health permits the collection of blood and blood components. (The SOPs may clarify that the responsible physician may make this determination by telephonic or other offsite consultation).