



Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

November 24, 1999

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VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-18

Jack I. Evan
Chief Executive Officer
Central Washington Hospital
1300 Fuller Street
Wenatchee, Washington 98801

WARNING LETTER

Dear Mr. Evan:

During an inspection of Central Washington Hospital's transfusion service and autologous donor collection center located at 1300 Fuller Street, Wenatchee, Washington on September 22, 23, 24 and 28, 1999, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations, Parts 600-680 (21 CFR 600-680) as follows:

1. Failure to store blood products intended for transfusion at required temperatures in that:
 - a. Platelets were stored, on at least 15 occasions, at temperatures outside the required 20-24°C without explanation [21 CFR 640.25(a)].
 - b. Fresh Frozen Plasma and Cryoprecipitated AHF were stored, on at least 86 occasions, at temperatures outside the required -18°C without explanation [21 CFR 640.34(b) and 21 CFR 610.53(c)].
2. Failure to determine the suitability of a donor as a source of Autologous Whole Blood on the day of collection [21 CFR 640.3] in that:
 - a. Autologous donors are not tested for an acceptable hemoglobin level prior to Whole Blood collection on their second donation. Autologous collection records indicated the second autologous unit is typically donated at a range of 7-15 days subsequent to the first donation.

3. Failure to maintain and/or follow written standard operating procedures to include all steps in the collection, processing, storage, and distribution of blood and blood products [21 CFR 606.100(b)] in that:
 - a) There are no written standard operating procedures for the thawing of Fresh Frozen Plasma or the thawing of Cryoprecipitated AHF. Our investigator observed this process to be performed without any controls by placing the blood products in a sink and running water over the product containers for an unspecified period of time.
 - b) There are no written standard operating procedures describing the solutions and methods to be used for arm preparation of a returning donor allergic to iodine. A donor indicated an allergy to iodine and records indicate that iodine was used to prepare the phlebotomy site when they returned for a subsequent donation.
 - c) Standard operating procedure Autologous Blood Draw: First Time Donor was not followed in that the venipuncture sites of two donors were observed to be scrubbed for 2, and 4, seconds respectively, rather than the 30 seconds required in the procedure.
 - d) Standard operating procedure Routine Release of Crossmatched Blood and Blood Products has not been updated to include computer operations utilizing [REDACTED] Blood Bank and Blood Donor System version [REDACTED]. Specifically, the procedure does not include what type of second verification of information entered into the computer should be performed when blood products are released from the blood bank. In addition, the current procedure for release of product requires that persons removing a blood product from the blood bank must verify the correct product is being issued. During three of four product releases observed during the inspection this verification step was not performed.
 - e) Standard operating procedure Standard Methodology Blood Bank Procedures has not been updated to reflect the use of [REDACTED] [REDACTED] Blood Bank and Blood Donor System version [REDACTED].
 - f) Standard operating procedures for equipment maintenance and quality control do not include procedures to address actions taken in response to temperature deviations for the platelet incubator and the product storage freezer, or for performing the volume verification for [REDACTED] Cell Washer.

- g) Standard operating procedure Quality Assurance for the Transfusion Service is not followed in that the quality assurance reviews of blood bank records are not being performed at least monthly.
- 4. Failure to observe, standardize and calibrate equipment on a regularly scheduled basis as prescribed in the standard operating procedures and Code of Federal Regulations [21 CFR 606.60(a) and 21 CFR 606.60(b)].
 - a) Blood container scales are not standardized against a known weight each day of use.
 - b) The [REDACTED] Serofuge was not calibrated upon receipt and the [REDACTED] Cell Washer was not calibrated following repairs as specified in the standard operating procedure.
 - c) The timers on the [REDACTED] Cell Washer and serologic centrifuges are not checked with a stopwatch as specified in the standard operating procedure.
- 5. Failure to adequately train employees to assure competent performance of their assigned functions [21 CFR 606.20(b)] in that:
 - a) Blood bank employees reported they began utilizing [REDACTED] Blood Bank and Blood Donor System version [REDACTED] on March 2, 1999. Training records indicate training on the new computer system occurred on April 30, 1999, May 3, 1999, and May 4, 1999. Employees operated a computer system that performs control functions related to the release of blood products for approximately two months before records indicate they were trained.
 - b) Two employees indicated on their competency assessment forms for the [REDACTED] Blood Bank and Blood Donor System version [REDACTED] that they did not know how to perform several blood banking procedures that are included in their responsibilities. There are no records to show that these employees were retrained.
 - c) An employee performing the arm preparations prior to the venipuncture of two autologous donors stated that she was not aware that the arm was to be scrubbed with iodine for 30 seconds, as stated in the standard operating procedure. She scrubbed the arm for 2, and 4, seconds respectively.

Jack I. Evan, Chief Executive Officer
Central Washington Hospital, Wenatchee, WA
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The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility as Chief Executive Officer to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Seattle District, Attention: Miriam R. Burbach, Compliance Officer.

Sincerely,


for Austin R. Long, Ph.D.
Acting District Director

cc: Grace Lynch
Chairman of the Board
Central Washington Hospital
P.O. Box 1887
Wenatchee, Washington 98801