HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Handling of Unsuitable Units		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

1.1 To establish system and set responsibilities for disposition process and documentation of all blood and blood components.

2. DEFINITONS:

2.1 **Unacceptable blood products** are defined as those that have serologically positive result, exceeded their expiry dates, do not pass visual inspection criteria, or that show abnormalities during labelling and discarded in-date.
2.2 **Quarantine:** To isolate nonconforming blood or blood components to prevent their distribution or use.
2.3 **Release:** Removal of product from quarantine status for distribution.
2.4 **Closed System:** A system, whose contents are not exposed to air or outside elements during preparation and separation of components. It means that the blood container should not be entered before issue except for the purposes of blood collection or transfer of components to a different container.
2.5 **Open System:** A system, whose contents are exposed to air and outside elements during preparation and separation of components.

3. POLICY:

3.1 This procedure provides instructions for how to remove and document the final disposition of blood products that have become unacceptable.
3.2 All blood and blood components that are found unsuitable for transfusion or for further manufacturing must be stored in a separate quarantine area until all TTD test results released and final disposition.
3.3 Proper quarantine and discard of positive blood components for blood-born transmitted diseases markers is essential for avoidance of transfusion-transmitted diseases.
3.4 All blood component units with positive screen TTD test results must be discarded from the first screen test results.
3.5 Identification and documentation of final disposal of unacceptable blood/blood products should be performed by two qualified staff members.
3.6 Discard unacceptable components before the initial labelling of blood and blood components.
3.7 Blood and components must be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

4. PROCEDURE:

4.1 **All Blood /blood components are quarantined under the following circumstances:**
- 4.1.1 Until serology and NAT results become available.
  - 4.1.1.1 Positive serological test result for anyone of the transfusion-transmitted disease, on the first screening test, will be discarded even if become negative by repeat screening or confirmation tests.
- 4.1.2 Confidential unit exclusion request by Donor (CUE).
- 4.1.3 A discrepancy exists between a units ABO/Rh type and the corresponding donors historical or tube results.
- 4.1.4 Permanently deferred donors units will be quarantined upon donation.

4.2 **Unacceptable blood products shall not be issued, discarded and documented including :**

4.2.1 Quantity not sufficient (QNS): weight < 316 gm plus weight of set (whole blood volumes of <300 ml).
4.2.2 Heavy units: >522 grams plus weight of set (whole blood volumes of >495 ml).
4.2.2.1 QNS and heavy units are disposed after the serology result becomes available.
4.2.3 Closed system compromised.
4.2.4 Presence of discoloration (e.g. deep yellow plasma), large clots, or hemolysis.
4.2.5 If an obvious abnormality is detected during labelling.
4.2.6 Blood/blood components with positive serological and/or NAT results.
4.2.7 Returning units after the permissible time or in unsuitable condition.
4.2.8 If the unit passed the expiration date.
4.2.9 Variances in procedure, resulting in units unsuitable for transfusion.
4.2.10 Polycythaemia patients units for therapeutic donation (If therapeutic donation becomes available in MCH).

4.3 **Procedure:**

4.3.1 All unscreened units are placed in a separate secured storage place, labelled "Unscreened", until serology and NAT results become available.
4.3.2 The process mandates discarding unacceptable components before the initial labelling of the products.
4.3.3 Identify units and components need to be quarantined or discarded, from a given donation number of the bags.
4.3.4 If whole blood was separated to its components, Blood bank technician will search for the all components to be discarded (tracking all blood units).
4.3.5 All unacceptable units will be discarded by two staff for identification and labelling of biohazard bag for discard then they will do process together by using hematos system of blood bank .
Steps of discard from hematos
4.3.5.1 At 1st label the product by production access then select label function the select all products of the donor that unsuitable then apply biohazard label on the bags and put it in quarantine area at refrigerator till the discarding process will be as following
4.3.5.2 On hematos system select production access then select operation then select discard ,enter your name ,press input then select the whole products of the affected donor number usually FFP,PLT,RBCs then select donor number then select the cause of discard from the list then the double check by hematos system by production access using product search function and be sure is written discarded
4.3.6 For units to be quarantined (and will never be used e.g. CUE), Attach to the units a quarantine and biohazard labels on each blood component to prevent erroneous releases.
4.3.7 The expiration date shall be identified as the last day on which the blood component should be used.
4.3.8 Record the final disposition of any unusable product, either in date or outdated in hematos system of blood bank or the waste disposal form including;
4.3.8.1 Unit number.
4.3.8.2 Product type.
4.3.8.3 Reason for product discard all.
4.3.9 Waste disposal forms are put in the specified file to form "Disposal of blood and blood components Register".
4.3.10 Discard all unusable products into biohazardous waste yellow bag.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records.**

5.1.1 Hematos system of blood bank
5.1.1 Waste disposal form
5.1.2 Disposal of blood and blood components Register

5.2 **Materials:**

5.2.1 Quarantine label
5.2.2 Biohazard label

6. RESPONSIBILITIES:

6.1 Blood bank staff members like technician/ specialist and supervisor of blood bank technicians or his deputy to follow the detailed procedures.

6.2 It's responsibility of Blood bank technician/specialist and supervisor together to identify of unacceptable blood products.

6.3 It's the responsibility of blood bank supervisor or his deputy to document the final disposition of any unusable blood product.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.

8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014.

8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.

8.4 AABB Technical manual, 18th edition, 2014.

8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Mohamed Amer	Blood Bank Physician		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 08, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 13, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025