Non-Technical SOP

Title	**Blood Component Irradiation**	
Prepared by	Stephanie Codina	Date: 2/15/2010
Owner	Stephanie Codina	Date: 2/15/2010

Laboratory Approval

Print Name and Title	Signature	Date
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

12 month (or new) management review and approval:
Signature acknowledges SOP version remains in effect with NO revisions.

Print Name	Signature	Date

Form revised 3/23/00

TABLE OF CONTENTS

1. PURPOSE

Blood components that contain viable lymphocytes (red blood cells, platelets, and granulocytes) may be irradiated to prevent proliferation of T-lymphocytes. Proliferation of T-lymphocytes causes transfusion-associated graft-versus-host disease (TA-GVHD), a disease in which donor lymphocytes engraft in the recipients and mount an attack on host tissue. Irradiated blood is prepared by exposing the component to a radiation source. The standard dose of gamma irradiation is 2500 cGy targeted to the central portion of the blood product container with a minimum dose of 1500 cGy delivered to any part of the component.

2. SCOPE

Red blood cell products, platelet products, and granulocyte products must be irradiated in the following situations:

- When requested by the treating physician
- When a directed-donor unit from any blood relative will be transfused
- When the recipient is receiving HLA-matched and/or crossmatched platelets
- When red cells and platelets are provided for neonatal transfusion, including exchanges and intrauterine transfusion.

SGAH blood bank will irradiate blood products for the WAH blood bank.

3. RESPONSIBILITY

All blood bank staff must demonstrate competency for component irradiation.

4. DEFINITIONS

1. Irradiator = a CIS Bio International IBL 437C
2. cGy = Centi-gray; also known as a rad. The real dose of energy per gram of tissue (blood product) delivered by irradiation.
3. Neonate = An infant <4 months of age.

5. PROCEDURE

A. Irradiation

Step	Action
1	Determine if the recipient needs blood product irradiation. **A.** When the physician requests irradiated blood products for the recipient, enter the marker into the LIS per procedure "Entering Special Transfusion Attributes into the LIS." **Once the irradiation marker has been added, all subsequent transfusions must be irradiated until a physician informs blood bank that transfusion of irradiated blood products is no longer clinically necessary.** B. All directed-donor blood products from all blood relatives will be irradiated. C. All HLA-matched and/or crossmatched platelets will be irradiated. D. All granulocyte products will be irradiated. E. All red blood cell and platelet products provided to neonates <4 months in age will be irradiated. This includes neonatal, exchange, and intrauterine transfusions. Note: Irradiation applies to cellular products only (red blood cell, platelet, and granulocyte products). Non-cellular products such as plasma and cryoprecipitate are not routinely irradiated.
2	Select a blood product that meets all patient criteria including blood type, antigen status, and any other special attributes.
3	Place a RAD-SURE label on each component to be irradiated (Refer to appendix A). A. Place the label on the front of the blood product below the product label. B. DO NOT cover any of the base label during application.  

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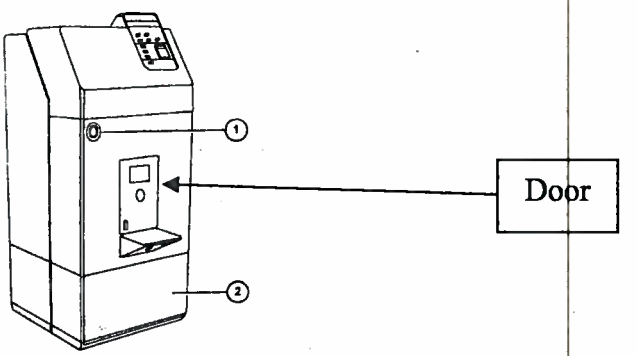
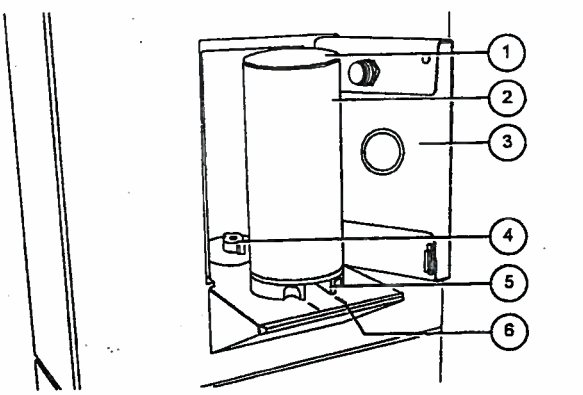
Step	Action
4	Place each component that needs to be irradiated into the basket. A. Do not commingle products that are not stored at the same temperature. Do not place red blood cells and platelets into the carrier at the same time. B. Do not irradiate more than two blood products at one time. C. Do not overfill the irradiation canister. There should be at least 1 inch of space between the blood products and the canister lid. D. The canister will accommodate a 60 mL syringe if you remove the yellow doughnut from the canister.
5	Replace the canister lid turning it counter-clockwise to lock it into place.
6	Open the door of the irradiation chamber. 
7	Make sure the drive pins are aligned with the picture engraved on the base plate of the irradiator. If the pins are not facing the correct direction, gently rotate them in a clockwise direction until they match the position of the picture.  1. Canister Lid 2. Canister 3. Door 4. Drive Pins 5. Recesses 6. Engraved Reference Mark

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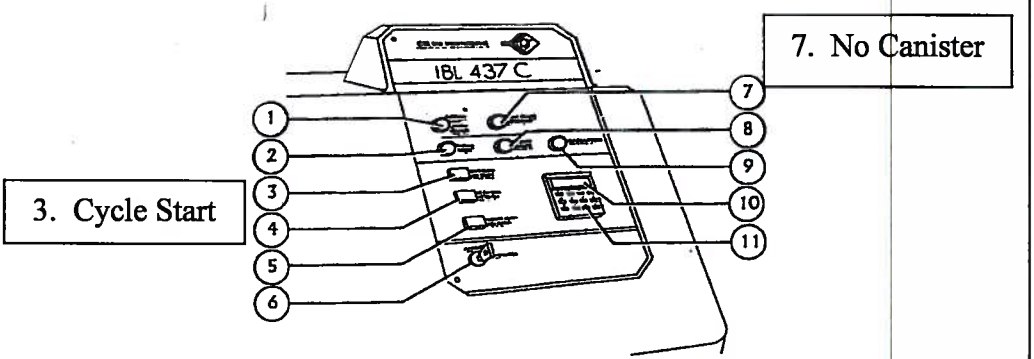
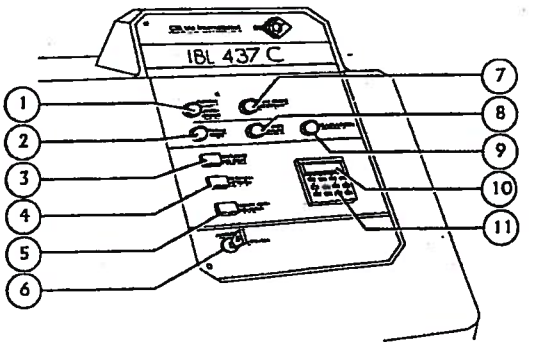
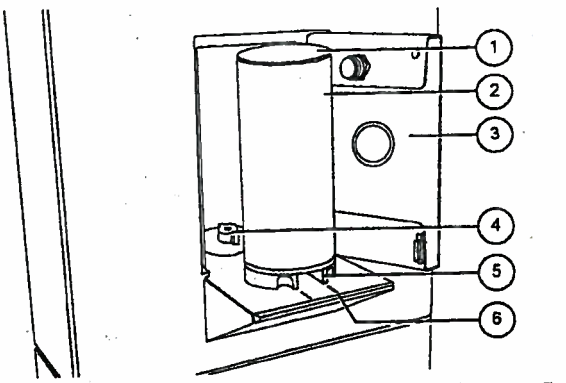
Step	Action
8	Set the irradiator canister onto the base plate and gently slide it towards the back of the chamber. When in position, the blue lines engraved on the base plate should align with the recesses on the bottom of the canister (see picture in step 7). If the basket is not positioned properly, the basket may not rotate properly.
9	Turn the canister 90° to the right in a clockwise direction in order to align the red engraved marker on the base plate with that on the canister.
10	Close the door. A. The "No Canister" indicator light should go out after the door is closed. B. When the basket is in the chamber and the door is closed, the "Cycle Start" switch will illuminate 

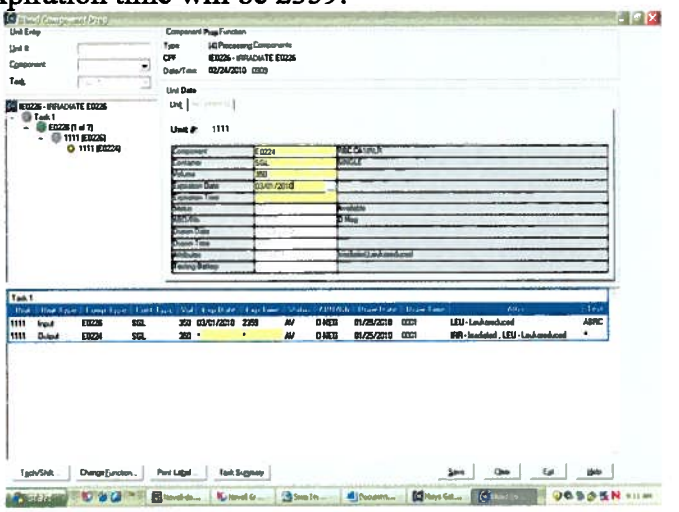
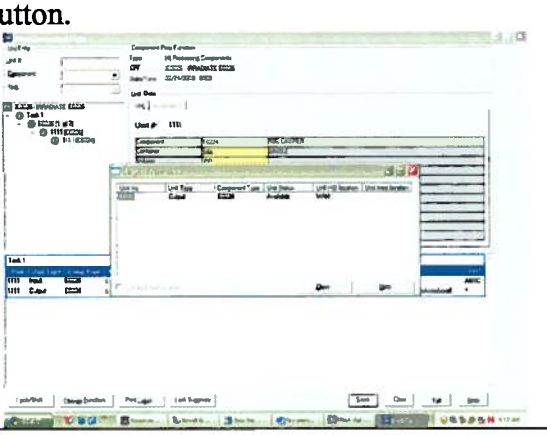
Step	Action
11	The IBL 437-C should always have the power turned (contact key) to the "On" position. Ensure the following indicator lights are illuminated: • Timer display screen (#10) • Mains (#2) • Battery (#8) Notify a supervisor if the lights are not illuminated.  1. Canister Rotation Light 2. Mains (On/Off Light) 3. Cycle Start 4. Test Lamps 5. Cycle Break 6. Key Switch (On/Off) 7. No Canister 8. Battery 9. Irradiation 10. Timer Display Screen 11. Timer Keyboard
12	Press the "Test Lamps" button. All indicators should light up except the "Test Lamps" indicator. Notify a supervisor if the lights do not illuminate.
13	The programmed irradiation time is calculated yearly at the time of preventative maintenance by Pharmalucence. Check timer display screen to make sure the correct time displays. DO NOT TOUCH ANY OF THE BUTTONS ON THE TIMER DISPLAY SCREEN.
14	Press the "Cycle Start" switch to start the irradiation cycle. At this time, the drum will begin its rotation (this can be seen by looking in the window of the door), the "Canister Rotation" light will blink, the "Irradiation" light will illuminate, and the time on the "Timer Display Screen" will count down. Observe that each of these occurs.

Step	Action
15	The irradiation cycle finishes when the programmed time has elapsed. The counter displays the value zero and the alarm will sound. A. Timer accuracy must be verified each day of use and canister rotation documented for each cycle. B. Refer to section F 'Quality Control' for details.
16	Open the door of the irradiation chamber to cease the alarm. A. The timer will reset to the previously programmed value. B. Turn the canister in a clockwise director in order to align the recesses at the bottom of the basket with the blue marks engraved in the base plate. C. Slide the basket towards the base plate until it releases. D. Remove the canister lid and blood products from the canister. E. Store the empty canister inside the chamber. Do not leave the canister on the platform of the loading chamber.  1. Canister Lid 2. Canister 3. Door 4. Drive Pins 5. Recesses 6. Engraved Reference Mark
17	Examine the "Rad-Sure" label for a black color. A. If the word "NOT" is visible, the unit did not receive the proper amount of irradiation and cannot be issued when the patient/situation requires irradiated blood products. B. Units that did not receive the proper irradiation dose cannot be re-irradiated.

Step	Action
18	Complete the "Component Irradiation Log" by filling in the following information. A. Tech performing irradiation B. Date of irradiation C. Unit number or donor identification number (DIN) D. Product code prior to irradiation E. Product code following irradiation F. Expiration date of original product G. Expiration date of irradiated product (28 days from date of expiration **or** original expiration date; whichever is first) H. Initial timer setting I. Ending timer setting J. Indicate whether the timer check was performed (see Quality Control) K. Indicate whether the canister rotated L. Indicate whether the word "NOT" is obscured on the rad-sure indicator label M. Time in and out of the storage container (refrigerator or platelet rotator)

B. LIS Documentation

Step	Action
1	Access Sunquest function "Blood Component Preparation."
2	At the "Value" prompt, type the code that is specific to the product type you are irradiating and press the "Tab" key. A. For Codabar Labeling a. IP is for CPDA-1, leukocytes-reduced red cell (04360) b. IPA is for Adsol, leukocytes-reduced red cell (04710 & 04730) c. IPP is for Apheresis platelet, leukocytes-reduced (12710) d. IPB is for Apheresis platelet, leukocytes-reduced, part 2 (12750) e. IPC is for Apheresis platelet, leukocytes-reduced, part 3 (12780) B. For ISBT-128 Labeling a. IE0226 is for product E0226 b. IE0336 is for product E0336 c. IE0382 is for product E0382 d. IE0424 is for product E0424 e. IE0678 is for product E0678 f. IE0686 is for product E0686 g. IE2857 is for product E2857 h. IE2866 is for product E2866 i. IE3077 is for product E3077 j. IE3087 is for product E3087 k. IE3088 is for product E3088 l. IE3089 is for product E3089

Step	Action
3	Press the "Tab" key twice more to default to the current date and time.
4	Click on the "Continue" button.
5	At the "Unit #" prompt, barcode the unit number.
6	Select the correct product type from "Component" dropdown menu.
7	Enter the new product expiration date and time in the appropriate fields. A. The expiration date will be the original product expiration date **or** 28 days from the time of irradiation **whichever is sooner.** B. The expiration time will be 2359. 
8	Click on the "Save" button.
9	The prompt, "File all units? OK/Cancel" will appear. Click on the "OK" button.
10	An "Output/New Units" screen will appear. Verify the information button and click the "Close" button. 

C. Labeling

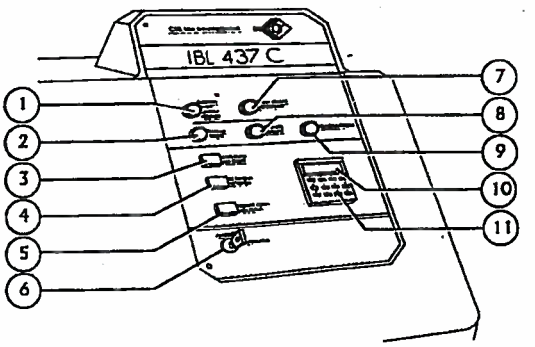
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>For ISBT-128 labeled units, print a new label using the Digitrax system. Refer to procedure, "ISBT-128 Label Production" for instructions.

For Codabar labeled units,
A. Apply the appropriate irradiated component label over the original component label as noted below by product code:

<table>
<tr><th>Pre-irradiation</th><th>Post-irradiation</th></tr>
<tr><td>04360</td><td>05360</td></tr>
<tr><td>04710</td><td>05710</td></tr>
<tr><td>04730</td><td>05730</td></tr>
<tr><td>12710</td><td>12810</td></tr>
<tr><td>12750</td><td>12850</td></tr>
<tr><td>12780</td><td>12880</td></tr>
</table>
B. Document the volume requirements on the new label using an ink pen.
C. Apply a "Prepared by Shady Grove Adventist Hospital Blood Bank" label to the bottom, right-hand side of the unit label. The Shady Grove label should be applied directly below the "Collected and Processed By" sticker that the blood manufacturer applied.
D. Edit the expiration date of the unit, if applicable.
a. The new expiration date is 28 days from the date of irradiation or the original expiration date of the unit whichever is sooner.
b. Drawing a single line through the current expiration date.
c. Write the date and your initials next to the line and old expiration date.
d. Write in the new expiration date.</td></tr>
<tr><td>3</td><td>Give the Product Modification Log and blood products to a second tech. The second tech will verify the labeling of the unit and check the appropriate box on the form for the following:
A. Correct expiration date
B. Correct component type
The second tech will then initial and date the "Label Verified By:" column of the form.
1. All labeling discrepancies should be fixed immediately and re-verified.
2. If only one tech is working, he/she may perform his/her own label verification checks.</td></tr>
</table>

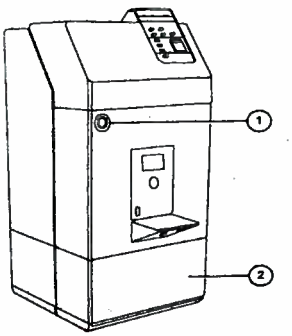
D. Troubleshooting

Step	Action
1	In situations where the cycle must be interrupted, A. Press the "Cycle Break" button. B. The corresponding red indicator light will illuminate. C. The drum will return to the loading/unloading position (ie facing the door). D. The timer counter will display the remaining time. E. Open the chamber door and remove the canister. When ready to resume the cycle, A. Replace the canister. B. Press the "Cycle Break" button a second time. C. The red indicator light will go out. D. The "Start Cycle" green light will illuminate. E. Press the "Start Cycle" switch and the timer will resume the countdown starting from the value reached at the time of the interruption.



1. Canister Rotation Light
2. Mains (On/Off Light)
3. Cycle Start
4. Test Lamps
5. Cycle Break
6. Key Switch (On/Off)
7. No Canister
8. Battery
9. Irradiation
10. Timer Display Screen
11. Timer Keyboard

Form revised 5/31/00

Step	Action
2	When extreme emergency situations such as smoke, fire, or insulation failure occur, A. Press the "Emergency Stop Punch." B. The equipment will be electronically disconnected, including the battery. C. The drum will remain in the position that it was in at the time of the disconnect. D. The counter will stop the countdown and will restore the time programmed at the beginning of the cycle. E. Notify a supervisor immediately. NOTE: This action can cause over-exposure of the blood products. The blood product **cannot** be issued if the "Emergency Stop Punch" was pressed during its irradiation cycle.  Emergency Stop Button

E. Power Failure

Step	Action
1	In the event of a power failure, the battery backup power supply ensures the return of the drum to the loading/unloading position. A. The "Mains" indicator light will flash. B. The "Cycle Break" indicator light will illuminate, indicating interruption of the cycle. C. The timer will store the remaining irradiation time at the time of the power failure. D. If the power is interrupted for less than 3 seconds, the irradiation cycle will not be interrupted.
2	All blood products must be immediately removed from the canister and returned to proper storage conditions in a power failure. The blood products should be returned to the canister and cycle continued with the remaining time when power is restored. To resume the cycle, A. Press the "Cycle Break" switch to acknowledge the interruption (the light will be blinking). B. The indicator light will go out. C. The timer countdown will resume from the value saved at the time of the power failure until the end of the cycle.

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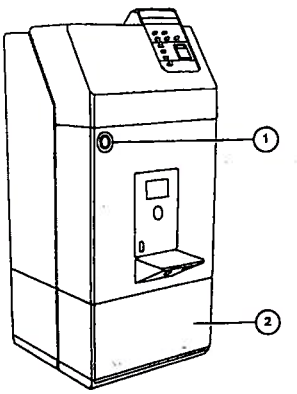
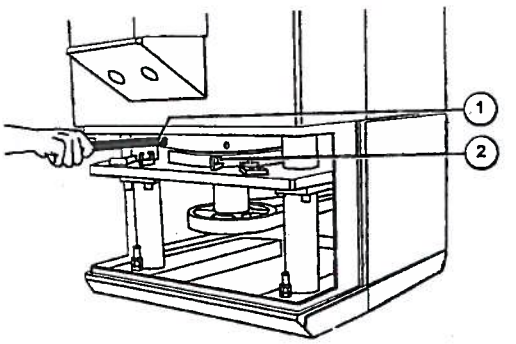
F. Basket Rotation Fault

Step	Action
1	The "Canister Rotation" light will stop flashing in the event of a fault or stoppage in the canister's rotation.
2	Press the "Cycle Break" button.
3	Look through the eye-piece of the door to see if the drum returned to the loading/unloading position. The drum should automatically return to the loading/unloading position.
4	If the drum does NOT return to the loading/unloading position: A. Press the "Emergency Stop Button" to disconnect the power supply. This is very important in preventing electrocution.  Emergency Stop Button Front Panel B. Remove the front panel of the machine and remove the safety control lever which is found in its holder.  C. Insert the lever into the holes of the cam-holder disc and turn the drum in a clockwise direction to the loading/unloading position. D. Look through the eye-piece of the door to visualize. E. Remove the blood products from the canister and return them to their proper storage conditions. F. Consult a supervisor for further instructions.

G. Emergency Procedures

Step	Action
1	The irradiator must be taken out of service **IMMEDIATELY** if the unit malfunctions during loading/unloading or during the irradiation cycle. Evidence of malfunction shall include binding of moving parts or the presence of metal shavings or chips. Press the emergency stop button if necessary to stop the irradiator.
2	Secure the room housing the irradiator.
3	Notify the Radiation Safety Officer and Pharmalucence.
4	Log and describe the abnormal occurrence(s) in the Blood Bank Communication Log.
5	DO NOT attempt to repair or modify the irradiator.
6	DO NOT attempt to operate the irradiator until clearance is obtained from either the Radiation Safety Officer or Pharmalucence.
7	Refer all questions regarding the safety of the irradiator to the Radiation Safety Officer.

6. RELATED DOCUMENTS

Form: Irradiator Log Sheet form (see Attachment Tab of Infocard)

7. REFERENCES

1. IBL 437C - Irradiator Type H Operator's Manual. CIS Bio International.
2. Standards for Blood Banks and Transfusion Services, 27th ed., 2011. AABB Publishing, Bethesda, Maryland.
3. CIS-US, Inc Technical Bulletin TB-001, Quarterly Safety Checks, 9/28/06.
4. Guidance for Industry, Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing, US Department of Health and Human Services, FDA-CBER, Feb 2000.
5. Circular of information for the use of human blood and blood components. Prepared by AABB, the American Red Cross, America's Blood Centers, and the Armed Services Blood Program. Bethesda, MD: AABB, 2009.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP SHB.012.001		
000	2/15/10	Updated owner Section 5: changed to table format and diagrams added, revised item B for LIS upgrade Section 9: added appendix A, renumbered subsequent appendices	S.Codina	N. Cacciabeve
001	4.25.11	Section 5: LIS documentation—Update BCP values; Section 6: Updated Irradiation Log Sheet; Section 9: forms moved to Related Documents; Deleted Component Modification Form	SCodina	NCacciabeve
002	10.9.12	Section 5: Updated criteria for irradiation, removed QC and calibration (moved to separate procedure) Section 6: Removed Rad-Sure SOP and QC form Section 9: Added Appendix A (Rad-Sure Indicators), removed Irradiation Time Calculation and Programming, renumbered subsequent appendices	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

A. Rad-Sure Indicator Labels
B. Indications for Blood Product Irradiation
C. COMAR Regulations

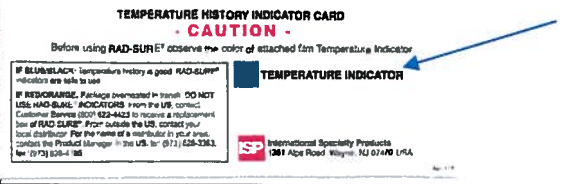
Form revised 3/21/00

Appendix A
Rad-Sure Indicator Labels

PURPOSE

When attached to blood products, Rad-Sure Type 15 indicators are a qualitative mechanism to indicate that a product has been exposed to radiation. They do not measure the quantitative dose from an irradiator or whether the IBL-437C is operating properly.

PROCEDURE

Step	Action
1	Each box of Rad-Sure indicators contains a temperature history indicator card. Verify the color of the temperature film. a. A blue black color indicates the Rad-Sure indicators have been maintained at an appropriate temperature range and the indicators are safe to use. b. A red/orange color indicates the Rad-Sure indicators have been exposed to excessive heat during transit. DO NOT use these indicators. Contact the manufacturer as indicated on the card. The manufacturer will send a replacement box of Rad-Sure indicators. 
2	Remove a sheet of Rad-Sure indicators from the box and look for the word "NOT" in the window of each indicator. **Do not use the indicators unless the word "NOT" is clearly visible.** 
3	Write the date of irradiation and your tech initials or tech code on the designated spaces on the indicator.
4	Peel the indicator from the backing and apply firmly to the appropriate clean, dry place on the blood product.
5	Irradiate the blood product per procedure, "Blood Component Irradiation."

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Step	Action
6	Following irradiation, check the indicator to verify that the window is black and obscures the word "NOT." The indicator should now read "IRRADIATED." Immediately notify a supervisor if the word "NOT" is still visible. 
7	Rad-Sure indicators are stored refrigerated at temperatures between 0-6°C. a. Prolonged exposure to heat and/or light can damage the indicators. b. The indicators must be stored away from all radiation sources, including gamma rays, electron beam devices, and microwaves.
8	Rad-Sure indicators cannot be used to calibrate an irradiator or measure radiation dosage. They are a qualitative indicator, not quantitative.

REFERENCE:

Rad-Sure Type 15 Gy and Type 25 Gy Blood Irradiator Indicator Package Insert, International Specialty Products, Rev 01-05.

Appendix B
Indications for Blood Product Irradiation

For All Patients	For Pediatric Patients	For Patients with Congenital Immune Deficiency
• Malignant lymphoma, from diagnosis to death • Currently or previously on purie analogue treatment (fludarabine, cladribine, 2-CDA, pentastatin) • Products from first- or second-degree relatives • HLA-matched components • Granulocyte components • Chronic graft-vs-host disease (GVHD) • on purine analogue drugs • Allogeneic marrow transplant from start of conditioning to end of GVHD prophylaxis • 7 days before harvesting of autologous stem cell transplant to 3 months after transplant or 6 months if total body irradiation is used • Aplastic anemia • Undiagnosed pancytopenia • ALL or AML for stem cell transplant	• All red cell and platelet transfusions given to infants <4 months of age • Intrauterine transfusions (IUT) of red cells or platelets • "Top-up" transfusions if previous IUT • Exchange transfusions (ET) or platelet transfusions following IUT • Any ET if delay for irradiation does not compromise care • Small blue cell tumors in childhood • Acute lymphoblastic leukemia (ALL) • Acute myeloblastic leukemia (AML) • Burkitt's lymphoma/leukemia • Solid tumors, eg o Ewing's sarcoma o Hepatoblastoma o Neuroblastoma o Osteogenic sarcoma o Retinoblastoma o Rhabdomyosarcoma • Langerhan's cell histiocytosis • Open-heart surgery in patient <6 months old	• Di George's syndrome • Congenital heart deficiency or open-heart surgery in patient <6 months old • Congenital cell-mediated immune deficiency • Severe combined immune deficiency • Wiskott-Aldrich syndrome • Purine nucleoside phosphorylase deficiency • Reticular dysgenesis • Adenosine deaminase deficiency • Major histocompatibility complex (HLA) I or II deficiency • Leukocyte adhesion molecular deficiency • Cell-mediated deficiency, not otherwise specified

Berte LM. Transfusion Service Manual of Standard Operating Procedures, Training Guides, and Competence Assessment Tools, 2nd ed. 2007. AABB Press: Bethesda, Maryland.

Appendix C
COMAR Regulations

Due to the presence of an IBL 437C Irradiator in the Blood Bank, the following guidelines are to be followed as additional controls in accordance with Maryland Code Ann., Env. Art. 8-501, COMAR 26.12.01.01 C.30(b), and COMAR 26.12.01.01C.50.

IC 1. The Irradiator is secured to prevent unauthorized access into the Blood Bank. The irradiator remains in a locked cage at all times to prevent unauthorized access. A second level of protection is offered by limiting access to the laboratory via locked doors.

a. Only the Blood Bank staff members who have been deemed trustworthy and reliable are permitted unescorted access to use the irradiator. A Blood Bank staff member is present in the room at all times.
b. All Blood Bank staff members are verified for employment by Quest Diagnostics Human Resources staff with background checks of previous employment, education, and references.
c. Routine maintenance is only conducted by an authorized NRC service provider. A member of the Blood Bank staff is present during routine maintenance.
d. A current list of Blood Bank staff members is posted.
e. The irradiator is contained within a locked cage within the Blood Bank. Only staff that has had a completed background check by the Nuclear Regulatory Commission is permitted to have unescorted access to the irradiator.

IC 2. Any unauthorized access to the radioactive material is documented and any action takenis according to the Shady Grove Adventist Hospital Radiation Contamination Accident Plan (Policy 38016).

IC 3. Any shipment of the licensed material is provided by the IBL 437C vendor CIS-US. The Blood Bank does not ship licensed radioactive material. All shipments are handled by the vendor Pharmalucence and will be required to meet all NRC guidelines. The Blood Bank will establish the time of delivery, confirm receipt of radioactive material, and notify vendor of any delay in receipt.

IC 4. There are no portable or mobile devices containing radioactive material in the Blood Bank.

IC 5. All documentation pertaining to these guidelines will be retained for 3 years after they are no longer effective.

IC 6. All documentation pertaining to these guidelines is to be maintained by the Blood Bank Supervisor and stored in the laboratory.