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| **Irradiation of Blood Products-MPLS** |
| **Purpose** | This procedure provides instruction for operation of the Rad Source 3400 or CIS-US IBL 437C Irradiator. |
| **Policy Statements** | * Absolute indications for irradiation of cellular blood component (RBCs, WBCs and platelets):
	+ Documented or suspected, acquired or congenital immunodeficiency disorders.
	+ Infants <4 months old throughout that admission period.
	+ Therapy induced immunosuppression, aggressive chemotherapy, immunotherapy, or extensive radiation therapy.
	+ Granulocyte concentrates/buffy coats.
	+ Directed donation form biologic relative.
	+ HLA-matched apheresis platelets/crossmatch compatible platelets.
	+ Exchange transfusion in newborns.
* Irradiation is not required for acellular components such as frozen/thawed plasma or cryoprecipitate.
* Leukocyte reduction is NOT an acceptable alternative to irradiation.
* Irradiated products may be used for any patient. Patient’s not requiring irradiation will be billed for a non-irradiated product charge.
* Positive HIV status is not an indication for irradiation.
* Solid organ transplant “candidate” does not require irradiation.
* The ordering provider shall indicate on the blood product order the need for irradiated products. All subsequent transfusions must be irradiated until the physician or pathologist determines irradiation is unnecessary.
* Information regarding the need for irradiation will be reflected tin the patient’s BAD file with PROBLEM comments UIRD or IR4 and the ATTRIBUTE of IRD. Refer to TS 5.3 Making change to a blood administration recorded.
* IR4 may be removed when a patient >4 months old is discharged or on re-admission.
* Gamma irradiation of 25 Gy (2500cGy) will be targeted to the central portion of the container to render the T-lymphocyte in the blood component incapable of replication thus prevent GVHD. A minimum dose of 15GY (1500cGY) shall be delivered to all other parts of the component.
* The expiration date of red cells products must be corrected to 28 days from the date of irradiation if the original outdate >28 days.
* Irradiate just prior to transfusion if possible due to the increased levels of potassium in stored irradiated blood.
* RBCs that have irradiated >72 hours should not be used for large transfusions (>20 mls per Kg)
* Irradiated products MAY NOT be returned to the Blood Center.
* In an emergency do not withhold blood products due to lack of irradiation. Notify the attending practitioner.
* The Blood Bank technologist should consult a pathologist if it is unclear why irradiated products have been ordered for a patient.
* Blood products should only be processed once in the Cycle Mode-RS 3400 only
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| **Related****Documents** | * TSf 10.8 Irradiation Logsheet
* TS 17.27 Using Radsure Irradiation Indicators.
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| **Materials** | **Equipment** | **Supplies** |
| * IBL 437C irradiator
* Rad Source 3400
 | * RAD-SURE® irradiation indicators 25 Gy, FDA registration #BK920035 (stored in small BB refrigerator)
* RAD-SURE® XR X-ray irradiation indictors 25 Gy, FDA registration #BK920035
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| **Quality Control** | TS 17.21 IBL 437C Blood Irradiator function verification and maintenanceTS 17.21.1 Rad Source 3400 Blood Irradiator function verification and maintenance |
| **Procedure** |  |
|  | **Step** | Action |
|  | 1 | Open the chamber door and remove the canister by aligning the large opening on the canister with the blue lines on the shelf. **Always turn the canister clockwise**.  |
|  | 2 | Place a RAD-SURE® Indicator on the selected unit(s).  |
| IBL 437C | 3 | Document the required information on the irradiation logsheet.  |
|  | 4 | Place the product(s) to be irradiated in the canister and replace the top.The number of units that can be irradiated in one batch is limited to:* 4 packed red cells
* 1-2 platelet pheresis
* 2 syringes
* Refrigerated and room temperature storage products **MAY NOT** be irradiated in

 the same batch. |
|  | 5 | Place the canister in the machine by aligning the propeller, then sliding the canister into place by lining up the large opening on the canister with the blue lines on the shelf. |
|  | 6 | Rotate the canister a quarter turn clockwise and lock into place by aligning the red indicator line on the outside wall of the canister with the red indicator line on the shelf. |
|  | 7 | Close the door. The NO CANISTER indicator light (1) will go off and the door will mechanically lock. |
|  | 8 | Verify or adjust the irradiator timer as to the posted 2500 cGy time. |
|  | 9 | Press the CYCLE START switch (4) to begin the irradiation cycle. The drum will start rotating. |
|  | 10 | Verify that the CANISTER ROTATION indicator light flashes to signal the exposure of the canister to the source and the start of the rotation of the canister. Document this on the irradiation logsheet.  |
|  | 11 | Verify that the machine is operating properly by checking the indicator lights. The CYCLE START light will go off as the process begins. |
|  | 12 | The irradiation cycle is automatically terminated when the set time has elapsed. The IRRADIATION light will go off when the blood product(s) is no longer exposed to the source. |
|  | 13 | When the canister is at the door, the door will mechanically unlock. The CANISTER ROTATION indicator light will go off. |
|  | 14 | Open the door to the chamber. Rotate the canister a quarter turn clockwise to release it from its holder. Align the large opening in the canister with the blue lines and remove the canister from the chamber. |
|  | 15 | Remove products from canister and observe RAD-SURE indicator. The window must be black and opaque, covering up the word "NOT". If the word “NOT” is clearly visible, notify the section technical specialist or lead.Note: A blood product may receive 2 cycles of irradiation for a maximum exposure of 5000cGY if the Radsure indicator was omitted on the first cycle or if the indicator/blood product was inadvertently placed in a position outside of the dose mapping field. |
|  | 16 | Complete the remaining required information on the irradiation logsheet. |
|  | 17 | Remove the blue “Not Irradiated” tag from the unit if attached. |
|  | 18 | Update the component type in the computer in function BCP.Reminder: The expiration date of red cells products must be corrected to 28 days from the date of irradiation if the original outdate >28 days. |
|  | 19 | Apply product over-label. |
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|  | **Procedure-Conditioning Routine**Notes:* The conditioning routine should be run if the condition lamp is on. If a STAT order must be irradiated, the conditioning cycle can be performed after the product is irradiated. The lamp will go out once the routine is completed. The condition lamp will light if the machine has not been in use for several hours or the machine has been turned completely off.
* If the machine is turned completely off, not in standby mode, it is recommended that the conditioning routing be run prior to normal use.
* The Key switch has three positions-Off; Condition; and Cycle.
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|  | Step | Action |
| Conditioning Routine | 1 | Open Chamber door and ensure the chamber is empty.**Note: The door release button must be pressed and held simultaneously when opening the door.** |
| Rad Source 3400 | 2 | Close the door gently |
|  | 3  | Ensure the Fault light is off.**Note: In normal operation this light is off**. |
|  | 4 | Turn the key switch to cycle and then to conditioning, press start within 3 seconds of the key turn to begin conditioning.**Notes:*** **If start button is not pressed within 3 seconds it will not start, repeat this step if necessary**
* **The Cycle Time Display will remain off. If the display comes on, the machine is in Cycle mode.**
* **Conditioning sequence and x-rays will begin**
* **X-ray Indicator Lights will flash**
* **The conditioning cycle will run for approximately 10-15 minutes**
* **The conditioning cycle should be run after each shift and recorded on the communication log**
 |
|  | 5 | Wait for the conditioning sequence to end* The condition lamp will turn off.
* X-ray Indicator Lights will stop flashing
* An audible tone will sound for approximately 15 seconds
 |
|  | 6 | The RS 3400 is ready for normal operation. |
|  | **Note: If the Cooling Required Lamp is illuminated, do not use: allow the machine to cool and the light to go off before use** |
|  | 1 | Prepare the canister(s) by verifying the Canister bottom is securely in place and remove the canister lid with the handle, if it is in place, so that you have access to the Canister for loading the blood products. **Note: Canister preparations steps can be performed at the beginning of the procedure to prior to placing products in the canister.** |
|  | 2 | Remove the products to be irradiated from storage.  |
| Irradiation Procedure Rad Source 3400 | 3 | Place a Rad-Sure® Indicator on the selected unit(s) |
|  | 4 | Document the required information on the irradiation logsheet. |
|  | 5 | Place a product into each canister.* Only one product per canister
* RBCs and platelets can be run in the same cycle in a different canister

**Note: The canister lid slots mark the volume lines for each canister. The product must fit between the slots at each end of the canister** |
|  | 6 | Twist the cap closed to the canister. |
|  | 7 | Open the chamber door. |
|  | 8 | Visually inspect the chamber to ensure the chamber and canister holders are empty.**Note: Be careful no to slam the canisters against the x-ray source.** |
|  | 9 | Insert the canister into the canister holder inside the chamber of the machine by pushing the canister retaining spring up.Note: Check that the canister is seated completely in the canister holder; the canister retaining spring will return to its original position.

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| **If** | **Then** |
| Irradiating more than one product,  | Repeat the steps for each canister |
| Irradiating one product, | Continue to next step |

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|  | 10 | Close the chamber door.* The magnetic latch will engage.

Notes:* If the door is not fully closed, the fault lamp will illuminated once the start button has been pushed and the cycle will not begin.
* If door is opened during the cycle, the door interlock will activate.
 |
|  | 11 | Turn the Key Switch to the Cycle position. |
|  | 12 | Verify the cycle time display is illuminated with the cycle time. |
|  | 13 | Run the irradiation cycle. |
|  | 14 | Press the start button.* X-ray indicator lights will illuminate for a few seconds.
* The x-rays will begin and the x-ray indicator lights will flash throughout the cycle.
* The cycle time display will begin counting down the seconds until the cycle is complete.

Notes:* NEVER stop a cycle once it has be started except in the case of an emergency by pressing the E-Stop button. The E-Stop button will need to be reset if used. To reset the button, push the button in and turn clockwise
* In the event the fault light illuminates during a cycle, see Fault Light and Buzzer Resume Feature at the end of procedure or TSja 10.8.1 RS 3400 Irradiator Troubleshooting Guide
* **CAUTION:** Do not disturb the cycle (do not open the door, do not turn the key, and do not shut off the machine.)
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|  | 15 | Wait for the end of the irradiation cycle. The buzzer will sound and its indicator light will activate.Note: If the buzzer does not sound and its indicator light does not activate refer to TSja TS 10.8.1 RS 3400 Irradiator Troubleshooting guide

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| **If** | **Then** |
| The fault Lamp illuminated during the cycle, once or more than once, | * Allow 30 seconds to pass after the fault lamp lights.
* Take picture of error codes
* Press the start button to restart the cycle.

Notes:* The irradiator will do a self-check which may take 5-10 seconds
* While the self-check is occurring the x-ray lights will both come on and the countdown timer will remain static until the self-check is completed.
* The irradiator will begin to complete the cycle and the countdown timer will continue
* Verify the cycle has completed. (Countdown timer is at zero).
 |
| The fault lamp does not illuminate during the cycle, | Continue with the next step. |

Additional notes:* If more than one fault occurs in the same cycle notify the technical specialist and complete a deviation form, the irradiator may need service.
* Per the vendor the blood products are still acceptable as long as the cycle completes.
* If more than 4 faults happen during the cycle the blood products needed to be quarantine
 |
|  | 16 | Press the door release button and open the chamber door simultaneously.* The buzzer and its indicator light will deactivate.
* The cycle time display will reset
 |
|  | 17 | Remove the canister(s) from the chamber. |
|  | 18 | Close the chamber door. |
|  | 19 | Unload product from the canister(s) and observe Rad-Sure® indicator. The window must be black and opaque, covering up the word “NOT”. If the work “NOT” is clearly visible, notify the technical specialist.**Note: If the Rad-Sure® indicator was omitted on the first cycle you CANNOT expose the product to another cycle** |
|  | 20 | Complete the remaining required information of the irradiation logsheet. |
|  | 21 | Remove the blue “NOT Irradiated” tag from the unit if attached. |
|  | 22 | Update the component type in the computer in function BCP. |
|  | 23 | Reminder: The expiration date of red cells products must be corrected to 28 days from the date of irradiation if the original outdate >28 days. |
|  | 24 | Apply product over-label. |
|  | 25 | Perform label check |
|  | **Fault Light and Buzzer Resume Feature**In the event a fault occurs during a Cycle, the operator can attempt to complete the Cycle. This can only be done if nothing has been disturbed to permanently terminate the Cycle. If nothing has been disturbed, then the operator should allow at least 30 seconds to pass after the fault light illuminated and then press the Start Button to Resume the Cycle. When this is done, the device will first check monitored components. The X-Ray Indicator Lights will both come on during this period and the Cycle Time Display will remain static until all items are checked by the device at which point it will then begin to complete the Cycle and The Cycle Time Display will resume.**Notes: Should refrain from using the “Resume Feature” more than three times within a single Cycle. If four faults happen within a single cycle or cannot complete a cycle at any time, contact Rad Source at 1-(678) 765-7900 and service@radsource.com** |
| **References** | 1. AABB Technical Manual, current edition
2. AABB Standards for Blood Banks and Transfusion Services, current edition
3. IBL 437C Irradiator for Blood Products Operator’s Manual, Compagnie ORIS Industries, France 1987
4. RS 3400 Operator’s Manual, Rad Source, 2019
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| **Approval****Workflow** | Transfusion Service/Medical Director |
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | J. Jaimez; | 8/13/93 | Initial Version |
| 2 | D. Hansen | 8/5/96 | New format |
| 3 | J. Wenzel | 11/17/1998 |  |
| 4 | D. Hansen | 9/1999 |  |
| 5 | J. Wenzel | 9/2001 |  |
| 6 | J. Wenzel | 5/01/2003 |  |
| 7 | J. Wenzel | 6/30/06 |  |
| 8 | J. Wenzel | 10/20/08 | New format |
| 9 | S. Cassidy | 04/10/2012 | CMS format |
|  | 10 | S. Cassidy | 04/09/2018 | Added statement on how long a RBC unit can be irradiated for large transfusions |
|  | 11 | S. Cassidy | 03/01/2021 | Added RS 3400 steps |