Beaumont HEALTH

Beaumont Laboratory
Dearborn

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IRRADIATION OF BLOOD COMPONENTS USING THE RAD SOURCE RS 3400 BLOOD IRRADIATOR

DB.BB.CP.PR.217.r07

Purpose

The purpose of this document is to provide policies and procedures applicable to the use of the Rad Source RS 3400 blood irradiator.

Principle

Irradiation of blood and cellular components is intended to prevent donor lymphocytes and monocytes from multiplying and producing antibodies to recipient antigens after transfusion in an effort to prevent transfusion associated graft vs host disease (TAGVHD). The Rad Source RS 3400 rotates individual canisters around a single cylindrical x-ray source for a specific period of time in order to deliver irradiation to the contents of the canisters evenly. The x-ray source is located within a lead-based shielding chamber to prevent x-ray radiation exposure to the operator and the surrounding environment. Individual blood component bags are placed inside each canister. A canister lid is affixed to each canister and the canister(s) are loaded into the canister holders within the irradiation chamber. Given the fixed x-ray source to canister distance, beam penetration and intensity, the dose delivered to blood or blood products is mainly a function of the duration of the irradiation cycle, which is established from the setting of the Rad Source RS 3400 timer.

Scope

Any platelets products that are considered non pathogen reduced (not treated with psoralen/UVA treated) and all granulocytes must be irradiated. Certain groups of patients require irradiated RBC components to prevent transfusion associated graft-vs-host disease (TAGVHD). The special message “Issue Irradiated Products” should be added to the computer record to identify patients who require irradiated blood products. For additional information refer to:

- P226, *Special Transfusion Requirements for Patients Greater than Four Months Old*
- P515, *Policies for the Selection of Blood Components for Neonatal Transfusion*

Policies

Granulocytes

Minimum Irradiated Inventory

A minimum inventory of irradiated stock will be maintained at all times to assure product availability when a product order request is sent to the Blood Bank. Staff will be responsible for checking stock and irradiating units as needed throughout each daily shift.

Table 217-1: Minimum Irradiated Inventory

Type	Minimum Units	Type	Minimum Units
O Positive	5	O Negative	5
A Positive	5	A Negative	5
B Positive	3	B Negative	2

AB Positive	0	AB Negative	0
Total Units	Minimum of 25 units irradiated		

Expiration Date of Irradiated Blood Components

- The expiration date of irradiated red blood cells (RBCs) is the **shorter** of:
  - 28 days from the date of irradiation, or
  - The original expiration date of the unit.
- For irradiated platelets and granulocytes, there is no change from the original expiration date due to irradiation.

Irradiation Indicators Affixed to Each Component before Irradiation

An irradiation indicator is affixed to each blood component before irradiation. For additional information, refer to P217A, *The Use of Irradiation Indicators for Irradiating Blood Components.*

- If a component was properly irradiated with the exception that the irradiation indicator was not affixed to the component before irradiation, then the policy *Partial Irradiation* applies.
- If individual platelet concentrates are irradiated before pooling, then an indicator is affixed to each concentrate.
- If a large volume platelet is received in two separate bags, it may be irradiated if volume is less than 500mL. The irradiation indicator shall be affixed to the primary bag only.

Powering Off the Irradiator

Typically, the Rad Source RS 3400 blood irradiator should never be turned off. If possible, the irradiator should always be powered on and ready to perform a Cycle mode if needed emergently. However, powering off the irradiator may be required to clear a fault if one occurs. Refer to the *Troubleshooting* section of this document.

If the Rad Source RS 3400 must be turned off following the completion of a normal cycle, it must be allowed to cool down for 5 minutes prior to turning the key switch to the “Off” position. If the Rad Source RS 3400 must be turned off to reset the E-Stop button, the key switch may be turned to the “Off” position immediately. See *Emergency Stop Button (E-Stop Button)* below.

Emergency Stop Button (E-Stop Button)

The E-Stop button can be used in an emergent situation to immediately stop all processes of the Rad Source RS 3400 blood irradiator. If the E-Stop button is pressed while blood products are being irradiated in Cycle mode, the cycle is considered void and incomplete. The E-Stop button should remain depressed until the situation is investigated and the emergency is resolved. To resume normal operation, turn the key switch to the “Off” position, turn the E-Stop button to release it, and then turn the key switch to the “Cycle” mode position.

Any blood products that are being irradiated in Cycle mode when the E-Stop button is pressed should be considered partially irradiated. Refer to the *Partial Irradiation Policy*.

Condition Mode

Condition mode puts the Rad Source RS 3400 through a periodic maintenance sequence that conditions the x-ray source. This Condition mode is required if the RS 3400 has not been in use for several hours, and is indicated when the Condition Light becomes

illuminated on the RS 3400 control panel. When the Condition Light becomes illuminated, the Condition mode must be completed as directed in *Procedure: Maintenance Sequence in Condition Mode* of this document prior to resuming normal use of the RS 3400 in Cycle mode.

Once completed, Condition mode does not need to be repeated until the Condition Light becomes illuminated again. That being said, Condition mode should be run proactively at the start of every shift in addition to whenever the Condition Light is illuminated. This will keep the RS 3400 in a usable state and help reduce possible delays when irradiation is required urgently.

Running an irradiation cycle in Cycle mode while the Condition Light is illuminated increases the risk of a fault occurring that will prevent the irradiation cycle from being completed successfully. If an emergent situation exists that requires the immediate irradiation of blood products while the Condition Light is illuminated, the Blood Bank Medical Director must be consulted to determine the appropriate action. Any time Cycle mode must be used while the Condition Light is illuminated, a variance must be written.

Cycle Mode

Cycle mode is the normal operation mode of the Rad Source RS 3400, and allows for irradiation of blood products.

Documentation of Irradiation

- Each time the irradiator is used, F-217, *Daily Preventative Maintenance, Quality Control, and Irradiation Record of the Rad Source RS 3400 Blood Irradiator* must be documented. This form includes documentation of the following:
    - The daily preventative maintenance and quality control.
    - Performance of the Conditioning Cycle
    - All irradiated blood products.
    - The irradiation indicator lot number and expiration date.
- Every blood product is documented in the computer to reflect the irradiation; refer to Triage CDM / *Change Blood Products*.

- Every blood product is labeled to reflect irradiation, as described in the DB.BB.CP.200 *Labeling Components* procedure

Use of F-217, *Daily Preventative Maintenance, Quality Control, and Irradiation Record of the Rad Source RS 3400 Blood Irradiator*

This form is designed to document the daily preventative maintenance, quality control, and the irradiation batches performed using the Rad Source RS 3400 Blood Irradiator for each day of use.

- The preventative maintenance and quality control must be completed and documented on F-217 each day of use before any blood products can be irradiated.
- Each day that the irradiator is used, a new F-217 should be filled out. There should not be irradiation batches from multiple days on the same form.
- If the irradiation indicator lot number or expiration date changes in the middle of a day, a new F-217 should be started. All blood products irradiated on a single F-217 form should be using the same irradiation indicator lot number or expiration date, which is documented under the daily maintenance and quality control section of the form.
- If F-217 has been completely filled up and additional irradiation batches are still required on the same day, a new F-217 should be started. The multiple F-217 forms for the same

day will be stapled together. The preventative maintenance and quality control section of the subsequent form does not have to be repeated. In this case, document that the daily PM and QC has already been performed in the "Additional Actions / Notes / Cleaning" column.

Using the RS 3400 Irradiation Canisters

The Rad Source RS 3400 has six individual canisters, allowing for irradiation of up to six blood products at a time.

- Only one blood product is permitted in a single canister. If a large-volume platelet is received from a blood supplier in two separate but attached bags, both platelet bags should be placed into the same canister as long as the canister lid can be securely affixed to the canister and the total volume of the platelet does not exceed 500mL. If the platelet does not fit or is above 500mL, the platelet cannot be irradiated in the Rad Source RS 3400. Refer to the policy *Non-Irradiation of Large Volume Double-Bagged Platelets* for additional information.
- A minimum of one blood product may be irradiated in a cycle.
- A maximum of six blood products may be irradiated in a cycle. Any combination of RBCs and platelets may be irradiated at one time. Note that it is not necessary to run the irradiator with the maximum number of blood products.
- Only canisters that contain blood products should be placed into the RS 3400 for an irradiation cycle; all empty canisters must be excluded during the cycle.
- Canisters containing blood products may be loaded into the RS 3400 irradiation chamber in any confirmation, regardless of the number of canisters used.
- All blood products are to be loaded in the canister in a way that allows the canister lid to securely affix to the canister.
- Products must be loaded so that any blood product tubing does not prevent each canister lid from closing.
- Frozen products may not be irradiated.

Prevention of Over- Irradiation

Blood products may receive too high a dose (over-irradiation) if the following sequence of events occurs:

- The cycle starts and then stops for any reason, and then
- The door is opened, and then
- The Start Button is pressed while the same units are in the irradiator.

DO NOT press the Start Button in this situation because the blood products may become over-irradiated. Once the chamber door is opened, the cycle is terminated and the Cycle Time Display will reset. If any blood products are over-irradiated, they must be discarded. This occurrence must be documented on a variance report.

Partial Irradiation Policy

There are instances in which we may consider blood components partially irradiated. Those instances are:

- If a component was properly irradiated with the exception that the irradiation indicator was not affixed to the component before irradiation.
- If the irradiation process is initiated (the Start Button has been pressed) and the canister(s) were removed before completion of the cycle.
- If a power surge or generator testing occurs while a cycle is in progress causing a fault that cannot be resumed.

Note: To help prevent this during times of generator testing, the key switch can be turned to the "Off" position, or simply leave the key switch in the "Cycle" position but do not perform any irradiation cycles until the generator testing is complete.

- If a fault occurred, and the canister(s) were removed instead of resuming the cycle where it left off.

  Note: For the first 3 faults, the cycle can be resumed after waiting at least 30 seconds. Upon the 4th fault, the cycle can no longer be resumed or completed. However, the blood products may still be considered partially irradiated if the irradiation indicators do not appear fully changed to "irradiated". Refer to the *Troubleshooting* section of this document.

If it appears that blood products are partially irradiated due to the above instances, an electronic variance shall be completed for review by the Supervisor and the Blood Bank Medical Director. F-217c, *Irradiator Fault - Variance Form* should also be documented to show which activity codes and lights are illuminated. The blood products should be placed in quarantine until reviewed by the Medical Director.

If it is determined by the Medical Director that the blood components are partially irradiated, then the following actions apply:

- The component must be labeled with F-217a, "Partial Irradiation / Do Not Irradiate" tag.
- The component must not be irradiated again.
- The component must be outdated as if it were properly irradiated; see the policy *Expiration Date of Irradiated Blood Components.*
- The product shall be modified to an irradiated product in the Blood Bank computer system and shall be labeled as an irradiated product.
- The irradiation indicator should be removed from the unit and attached to the variance.
- F-217a (the tag) should be removed from the blood product before it is issued; attach it to the dispense copy of the *Record of Transfusion*.
- The partially irradiated blood product shall not be issued to a patient who requires irradiated blood products.
- Partially irradiated blood products shall not be transferred to another facility.

Non-Irradiation of Large Volume Double-Bagged Platelets

If a large volume double-bagged platelet is received from a blood supplier, the platelet may not fit inside one of the Rad Source RS 3400 irradiation canisters. If the platelet does not fit into an irradiation canister, or the platelet is above 500mL, the platelet cannot be irradiated in the Rad Source RS 3400. These platelets will stay un-irradiated and should be given to patients that do not require irradiated products. If there is any uncertainty as to whether the platelet can be given to a patient, the Blood Bank Medical Director should be consulted to determine the appropriate action.

Policy Regarding the Type of Blood Product Bag that can be Irradiated

Blood products can only be irradiated if they are in the original blood product bag. Irradiating products that are in transfer bags, syringes, or "donuts" (from the COBE 2991 Blood Cell Processing Set) have not been cleared by the FDA and therefore is not permitted.

Rad Source RS 3400 Cooling System and Cooling Required Light

The Rad Source RS 3400 has an air to liquid heat exchanger cooling system that utilizes a 10 gallon internal supply of distilled water. This system eliminates the need for an external

water connection, and should not normally require any employee involvement other than verifying the water is not leaking from the irradiator. The water level will be checked and filled as needed by Rad Source Technologies, Inc. service technicians at every annual maintenance and field service call. Refer to P323, *Preventative Maintenance and Quality Control of the Rad Source RS 3400 Blood Irradiato*r.

The Rad Source RS 3400 has a Cooling Required Light on the control panel that indicates when the internal coolant temperature has exceeded the acceptable limit. When the Cooling Required Light is illuminated, no cycles shall be run. Once the temperature of the coolant has decreased into the acceptable temperature range, the Cooling Required Light will turn off and normal use of the irradiator may resume. If a cycle is attempted while the Cooling Required Light is illuminated, a fault may activate.

Irradiation Timer Check
This check is performed following any service from Rad Source service personnel, and following any situation where the irradiation cycle time has been adjusted. For additional information, refer to P323, *Preventative Maintenance and Quality Control of the Rad Source RS 3400 Blood Irradiato*r.

Definitions
- **QC:** Refers to quality control.
- **PM:** Refers to preventative maintenance.

Equipment
Rad Source RS 3400 Blood Irradiator

Supplies
- Irradiation indicators

Forms
- F-217, *Daily Preventative Maintenance, Quality Control, and Irradiation Record of the Rad Source RS 3400 Blood Irradiator*
- F-217a, *Partial Irradiation / Do Not Irradiate* tag
- F-217c, *Irradiator Fault – Variance*
- F-303c, *Equipment out of Service*

Equipment Maintenance / Quality Control
- Refer to P323, *Preventative Maintenance and Quality Control of the Rad Source RS 3400 Blood Irradiator.*

Special Safety Precautions
- X-ray radiation is a form of ionization radiation that is potentially very hazardous. Failure to understand the safety information within the *RS 3400 Operator's Manual* could result in unsafe radiation exposure.
- For additional information refer to the *Radiation Safety Notice* that is posted on the irradiator.

Procedure: Maintenance Sequence in <u>Condition Mode</u>

Condition mode should be run whenever the Condition Light on the control panel is illuminated. Refer to policy section *Condition Mode* for additional information. Run Condition mode as follows:

1. Make sure the RS 3400 key switch is in the "Cycle" mode position.

2. Ensure the RS 3400 irradiation chamber is empty of all blood products and canisters. To do this, press the Door Release Button while simultaneously pulling open the chamber door gently.

3. Gently close the chamber door so the door latching magnet engages, preventing the chamber door from opening inadvertently.
   The chamber door should never be slammed, rapidly opened, or rapidly closed.

4. Make sure the Fault Light on the control panel is off. If the Fault Light is illuminated, do not continue with Condition mode.
   Refer to the *Troubleshooting* section of this document.

5. Turn the RS 3400 key switch to the "Condition" mode position and immediately press the Start Button.
   a. If the Start Button is not pressed within 3 seconds of placing the key switch into the "Condition" mode position, the Start Button is deactivated and the procedure must be restarted from step 1.

6. The following will occur once the Start Button is pressed and the Condition mode starts:
   a. Both X-Ray Indicator Lights will illuminate temporarily, followed by alternating flashing of the X-Ray Indicator Lights for the remainder of the cycle indicating the x-ray source is active.
   b. The Cycle Time Display will NOT display and will remain completely blank.
   c. The Condition mode will continue for several minutes (about 10 -15 minutes).

7. Upon completion of the Condition mode, the Cycle Completion Buzzer will activate and the small red Cycle Complete indicator light will illuminate for approximately 15 seconds.

8. Verify the Condition Light is no longer illuminated.
   If the Condition Light is still illuminated following the completion of Condition mode, refer to the *Troubleshooting* section of this document.

9. Once Condition mode is performed successfully and the Condition Light is no longer illuminated, the RS 3400 may be used to irradiate blood products using the Cycle mode.
   Refer to *Procedure: Irradiation of Blood Components in Cycle Mode.*

Procedure: Irradiation of Blood Components in <u>Cycle Mode</u>

1. Perform the daily preventative maintenance and quality control, if applicable. Document this process on F-217, *Daily Preventative Maintenance, Quality Control, and Irradiation Record of the Rad Source RS 3400 Blood Irradiator* in the Preventative Maintenance and Quality Control Section.
   Refer to P323, *Preventative Maintenance and Quality Control of the Rad Source RS 3400 Blood Irradiator* for additional information.

2. Make sure the RS 3400 key switch is in the “Cycle” mode position.

3. Verify the Condition Light on the control panel is not illuminated. If the Condition Light is illuminated, Condition mode must be ran prior to irradiating blood products in Cycle mode.
   Refer to *Procedure: Maintenance Sequence in Condition Mode.*

4. Verify the Fault Light on the control panel is off. If the Fault Light is illuminated, do not continue with Cycle mode.
   Refer to the *Troubleshooting* section of this document.

5. Document the irradiation indicator lot number and expiration date being used on F-217. When performing subsequent irradiation batches within the same day, verify that the irradiation indicator information matches the ones currently being used.
   If the irradiation indicators being used have a different lot number or expiration date than what is documented on F-217, a new F-217 must be started.

6. Document F-217 with the employee, time, and blood products that are being irradiated.

7. Review the product description on the face label of each product to make sure that it has not already been irradiated. Affix an irradiation indicator to each blood product to be irradiated**.**
   Refer to P217A, *The Use of Irradiation Indicators for Irradiating Blood Components.*

8. Load the blood product(s) into the canister(s) as follows:
   a. Obtain an irradiation canister for each blood product that is to be irradiated.
   b. Place each canister securely in place and remove the canister lid with the handle.
   c. While each canister is standing upright on the counter or loading shelf, or being held in the employee’s hands, carefully and gently insert the blood product into the canister.
      i. Only one blood product is permitted in each canister.
      ii. The canister lid slots mark the volume limit of the canister. Verify the blood product is below the canister lid slot to ensure it will not inhibit the lid from properly fitting onto the canister.
      iii. Verify there are no large metal objects attached to the blood product bag or located inside the canister. Standard metal sealing clips attached to blood product bags are acceptable.
   d. Attach a canister lid to each canister that contains a blood product.

   Refer to the policy *Using the RS 3400 Irradiation Canisters.*

9. Press the Door Release Button while simultaneously pulling the chamber door gently to open up the irradiation chamber.

10. Verify the irradiation chamber is empty and that there is nothing inside any of the canister holders.

11. Place each canister that contains a blood product into an available canister holder by slightly pushing the canister retaining spring up (the canister itself may be used for this purpose) and inserting the canister all the way into the canister holder. Once the canister

is pushed all the way into the canister holder, the retaining spring will return to its original position, gently securing the canister in the canister holder.

a. The loaded canisters may be placed in any configuration within the chamber, regardless of the number of canister used.
b. Do not load empty canisters into the chamber.
c. Assure the canister lid is secure prior to loading the canister into the canister holder.
d. For easier removal, orient the canister so that the canister lid slots are not located at the canister retaining spring.
e. Do not rotate the canister within the canister holder once it has been loaded. This could cause the canister lid to loosen and fall off during a cycle.

The canister must be fully inserted into the canister holder in order for the blood products to be in the proper irradiation field. The canister retaining spring should never be compromised in any way and must always be present.

12. Visually inspect the entire irradiation chamber to ensure the canister retaining spring on each canister holder is in a horizontal position and the handles on the canister lids are facing toward the employee.

13. Close the chamber door gently ensuring the door latching magnet engages to lock the chamber door tight.
    The chamber door should never be slammed, rapidly opened, or rapidly closed.

14. Verify the Cycle Time Display is illuminated and displays the cycle time (less than 5 minutes).

15. Press the Start Button. The following will occur after the Start Button is pressed:
    a. Both X-Ray Indicator Lights will illuminate temporarily, followed by alternating flashing of the X-Ray Indicator Lights for the remainder of the cycle indicating the x-ray source is active.
    b. The Cycle Time Display will count down the seconds remaining until the Cycle mode is complete.

- Never interrupt a cycle once it is started, except in the event of an emergency.
- The countdown timer automatically resets when the chamber door is open, the key switch is turned from the “Cycle” mode position, or the mains power breaker switch is turned off.
- If the cycle is interrupted and cannot be resumed without resetting the countdown timer, refer to *Partial Irradiation Policy*.

16. Upon the completion of the Cycle mode, the Cycle Complete buzzer will activate and the small red Cycle Complete indicator light will illuminate. Both of these cycle completion indicators will remain active until the chamber door is opened, at which point they will stop and the Cycle Time Display will reset.

If either cycle completion indicators fails to activate, or the Fault Light is illuminated, the Cycle mode was not properly completed. Refer to the *Troubleshooting* section of this document.

17. Press the Door Release Button while simultaneously pulling the chamber door gently to open up the irradiation chamber.

18. Remove all canisters from the chamber and assure the chamber is empty. Gently close the chamber door.
    A Canister should never be removed from the canister holder by grabbing and pulling on the canister lid handle. Instead, grab the canister where the finger notches are located on the canister holder.

19. Remove the blood products from the canisters. Verify that the irradiation indicators display as irradiated for each blood component and complete the documentation of F-217.
    If the indicator does not display as irradiated after the irradiation cycle, then the blood component must be considered partially irradiated; refer to the *Partial Irradiation Policy*.

Troubleshooting

The Rad Source RS 3400 Blood Irradiator *Operator's Manual* includes information on faults, maintenance, and service. As indicated in this *Troubleshooting* section, faults may occur that may automatically stop the irradiator. Additional troubleshooting information may be available from:

- Rad Source Technologies, Inc.: (678) 765-7900
- Beaumont Health Biomedical: (248)-551-6300

Faults

If the Rad Source RS 3400 blood irradiator detects that any of the internal operations are functioning outside of their set parameters, a fault may occur. When a fault occurs, the Fault Light on the control panel will illuminate and the Fault Buzzer will sound. The Fault Light and Buzzer will remain activated until the fault is resolved or cleared, as described below.

- If a fault occurs while irradiating blood products in Cycle mode, the Cycle Time Display will pause and the Fault Light will illuminate.
    - In this case, the employee can attempt to resume and complete the cycle after documenting F-217c, *Irradiator Fault – Variance*. This can only be done if nothing has been disturbed to permanently terminate the cycle (e.g., opening the chamber door, shutting the device off, pushing the E-Stop button, etc.).
    - If nothing has been disturbed, wait at least 30 seconds from when the Fault Light becomes illuminated and then press the Start Button to resume the cycle.
    - When this is done, the device will first check monitored components (this may take a few seconds). The X-Ray Indicator Lights will both illuminate during this period (about 5 -10 seconds) and the Cycle Time Display will remain paused 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 counting down.
    - This cycle resume feature may be done up to three times during a cycle, while waiting 30 seconds from the illumination of the Fault Light each time. Each time a fault occurs during a cycle, the next section of F-217c, *Irradiator Fault – Variance* form must be documented (e.g., *Fault #1*, *Fault #2*, etc.). If the cycle resume feature is successful in continuing and completing the

irradiation cycle, the blood products may be processed and treated as fully irradiated.
    - If a fourth fault occurs during a cycle, or the cycle cannot be completed for any reason, refer to *Handling a Fault when the Cycle Cannot be Resumed or Completed* below.
- If a fault occurs at the beginning of a cycle because the door latching magnet is not fully engaged or the Cooling Required Light is illuminated when the Start Button is pressed, then the Fault Light will illuminate, the Fault Buzzer will sound, the Cycle Time Display will not illuminate, and the device will not produce any x-rays. If a fault occurs due to this situation, Rad Source Technologies does not need to be contacted. Refer to *Blood Product Disposition when a Fault Occurs at the Beginning of a Cycle, Prior to Activation of the X-Ray Source* below.

Handling a Fault when the Cycle Cannot be Resumed or Completed
Whenever a fault occurs that cannot be resumed or prevents the cycle from being completed, Rad Source Technologies should be contacted and the irradiator should not be used until the fault has been reviewed and resolved.

- Place *Equipment out of Service* on the irradiator.
- Documenting F-217c, *Irradiator Fault – Variance* to indicate which lights and activity codes are being displayed and document an internal variance.
- Contact Rad Source Technologies, Inc. at (678) 765-7900.
- Once the information displayed on the irradiator has been documented on F-217c, *Irradiator Fault – Variance,* the fault may be cleared to deactivate the Fault Light and Fault Buzzer by turning the key switch to the “Off” position.

Normal use of the Rad Source RS 3400 should not occur until Rad Source Technologies have been consulted, the fault has been reviewed, and the irradiator is deemed acceptable to resume normal use by the Blood Bank Medical Director. Note that a mock irradiation cycle using saline-filled transfer bags affixed with irradiation indicators is included in the return to use process.

Blood Product Disposition when the Cycle Cannot be Resumed or Completed
If the cycle cannot be resumed or completed, the irradiation indicators on the blood products should be visually inspected. If the irradiation indicators do not appear fully changed to “irradiated”, it can be assumed that the blood products have not received a full irradiation dose and can therefore be considered partially irradiated, regardless of the reason for the fault. If the irradiation indicators do appear as fully “irradiated”, we are unable to determine how much over the acceptable dose of irradiation the blood products received. In this instance, the Blood Bank Medical Director should be contacted to determine the disposition of the blood products based on information received from the irradiator’s activity codes and consultation from Rad Source Technologies, Inc.

Blood Product Disposition when a Fault Occurs at the Beginning of a Cycle, Prior to Activation of the X-Ray Source
If a fault occurs at the beginning of a cycle and the x-ray sources were never activated (the X-Ray Indicator Lights never illuminated), the blood products did not get any exposure to x-ray radiation and the units may still be irradiated again. This might occur because the door latching magnet is not fully engaged, or the Cooling Required Light is illuminated when the Start Button is pressed.

Fault Light Illumination due to the Failure of the X-Ray Indicator Lights
Failure of one of the two X-Ray Indicator Lights during operation will result in that particular light not operating and the Fault Light will then flash as the failed light normally would. This will not stop the cycle in progress; however, the failed light should be replaced immediately so the X-Ray Indicator Lights operate normally. Until the failed X-Ray Indicator Light is fixed, additional irradiation cycles will not be possible. Notify a supervisor or MT Lead if this occurs.

Should both X-Ray Indicator Lights fail, the Fault Light will flash at a high rate, indicating the failure and the device will no longer operate until the X-Ray Indicator Lights are fixed. Refer to P323, *Preventative Maintenance and Quality Control of the Rad Source RS 3400 Blood Irradiato*r.

References

- AABB *Standards for Blood Banks and Transfusion Services*, standard 5.1.8A, *Requirements for Storage, Transportation, and Expiration*, twenty-seventh edition.
- Rad Source RS 3400 Operator's Manual, MKT-006, Revision 7, November 04, 2020
- Email memos from Brian Baroud, Account Executive and Rich Adams, Vice President, Rad Source Technologies, Inc., December 22, 2020 – December 31, 2020.

Attachments

- P217A, *The Use of Irradiation Indicators for Irradiating Blood Components.*
- Job Aid: *Examples for Documenting F-217.*
- Job Aid: *Minimum Irradiated Inventory.*

Authorized Reviewers

Chief, Pathology and Laboratory Medicine
System Medical Director, Lab Transfusion Services
System Manager, Lab Transfusion Services
Department Supervisor, Lab Transfusion Services

IRRADIATION OF BLOOD COMPONENTS USING THE RAD SOURCE RS 3400 BLOOD IRRADIATOR

Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S**:/** Master printed document stored in the *Transfusion Medicine Standard Operating Procedure Manual*.
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 2
Location of circulating Controlled Copies: One copy of the *Job Aid: Examples for Documenting F-217, Irradiation Record* is located on the irradiation clipboard. One copy of the *Job Aid: Minimum Irradiated Inventory* is located next to the irradiated shelves on the wall.

Document History

Signature	Date	Revision		Related Documents Reviewed/ Updated
Prepared by: Kelly Sartor	04/20/2020	04	Standardized procedure number, policies and format with BHS	YES
Approved by: J.T. Powers, MD	04/28/2020			
Reviewed by: (Signature)	**Date**	**Revision**	**Modifications**	**Related Documents Reviewed/ Updated**
Revised by: Kelly Sartor	10/06/2020	05	Added specific verbiage for thawed/deglycerolized RBC to the policy regarding what types of bags can be irradiated.	Yes
			Changed Authorized reviewers.	
Approved by: J.T. Powers, MD	10/07/2020			
Revised by: Kelly Sartor	01/21/2021	r06	Completely revised for the use of the new Rad Source RS 3400 irradiator. Removed reference to F-217A, *Opening a New Box of Irradiation Indicators* since the form is retired. Updated references, attachments, and authorized reviewers. Added policy section *Non-Irradiation of Large Volume Double-Bagged Platelets* since some large volume platelets cannot be irradiated in the RS 3400.	
Approved by: J.T. Powers, MD	02/12/2021			
Revised by: Kelly Sartor	05/07/2021	**R07**	Removed irradiation requirement for Pathogen Reduced (Psoralen/UAV Treated Platelets)	
Approved by: J.T. Powers, MD	05/07/2021			