**PURPOSE:**

To provide instruction for irradiating blood components using the Rad Source RS 3400 X-Ray Blood Irradiator

**PRINCIPLE & CLINICAL SIGNIFICANCE:**

**Principle**

Irradiation of cellular components is currently the only reliable method to prevent Transfusion-Associated Graft vs. Host Disease (TA-GVHD). Per AABB Standards, a minimum dose of 25Gy delivered to the center area of the container with a minimum of 15Gy everywhere else is required

**Clinical Significance**

TA-GVHD is a complication of blood transfusion where transfused lymphocytes mount an immune response against the recipient and is usually fatal. Patients considered at risk for include the following:

* Fetuses/infants receiving intrauterine or exchange transfusions
* Recipients who had or are preparing to undergo a bone marrow, cord blood or

peripheral blood progenitor cell transplantation

* Recipients of directed donor units known to be from a blood relative
* Recipients of HLA-selected or crossmatched platelets
* Recipients of granulocyte transfusions
* Recipients with congenital immune deficiency
* Recipients with hematologic malignancy or solid tumor (neuroblastoma, sarcoma, Hodgkin disease)

TSL Medical Staff may approve irradiated components for other clinical indications.

**POLICIES:**

* The following blood components must be irradiated:
* All cellular components issued to infants <1 year old (including cellular components issued for intrauterine transfusions and exchange transfusion
* All cellular-components distributed to the SCCA
* All cellular components issued to UWMC inpatients with an SCCA flag in Sunquest
* HLA-matched or crossmatch platelets
* Directed donor unit from blood relatives
* Granulocytes
* Any irradiaton orders the TSL Medical director approves for immune-incompetent or immunocompromised recipients
* Irradiation requests not meeting the above criteria should be reviewed by the TSL MD. If the TSL MD is not available at the time of order, the irradiation request should be honored until the review can be performed
* Irradiation Cycle load limits
  + Minimum Load: Canister holds one adult unit or one syringe holder loaded with 1 to 3 syringes
  + Maximum load: six adult units or 4 adult units and 6 syringes
* A Rad-Sure indicator label must be adhered to each component prior to irradiation. The indicator film must blacken obscuring the NOT irradiated film after the component is irradiated - Example: Go to [Interpretation](#Interpretation) below
* Radiation Oncology will irradiate blood components in the event the RadSource Blood Irradiator is out of service and there is not enough irradiated stock to meet patient needs. The TSL Medical Director should be contacted and approve the use of Radiation Oncology services.

**SPECIMEN REQUIREMENTS:**

NA

**REAGENTS/SUPPLIES/EQUIPMENT:**

|  |  |  |
| --- | --- | --- |
| **Reagents:** | **Supplies:** | **Equipment:** |
| * NA | * Canister * Syringe Holder * Rad-Sure XR 25 Gy indicator labels * Rubber bands * Luer lock caps * Irradiator Tablet Downtime Log * Plexiglass cases (for use with linear accelerator) | * Irradiator * Rad-Source Tablet/ Barcode Scanner |

**QUALITY CONTROL:**

* Rad-Sure XR 25 Gy Indicator labels are inspected upon receipt and used and stored at temperatures of 1-6⁰C

**INSTRUCTIONS:**

**TABLE of CONTENTS**

[**Running Irradiation Cycle**](#Running)

[**Verifying and Documenting Irradiation**](#Verifying)

[**Fault Recovery**](#fault)

**Back-up [Irradiation by Radiation Oncology Linear Accelerator](#Linear)**

**Running Irradiation Cycle**

|  |  |  |
| --- | --- | --- |
| **STEP** | **ACTION** | |
| **1** | Verify the ‘conditioning light’ is not illuminated   |  |  | | --- | --- | | **If the conditioning light is** | **Then** | | Not illuminated | Go to next step | | Illuminated | Run a conditioning cycle prior to irradiating the blood component   1. Verify irradiator is empty 2. Turn key to Condition 3. Press Start | | |
| **2** | Date and initial a Rad-Sure indicator label and adhere the label to the component without obliterating other required labeling elements (the word ‘**NOT**’ will be visible through the red film) | |
| **3** | Verify the key is in the “CYCLE” position |  |
| **4** | * Log into the tablet by pressing the power button if the screen has darkened and swiping the screen up * Enter the password 1234, if prompted | |
| **5** | Open RSTScan program if not already open  **NOTE:** If RSTScan program is not available for use, record downtime testing on *Component Irradiation Log* | |
| **6** | Scan the following into the appropriate field on the tablet (cursor should automatically move to the next field) using the handheld scanner   |  |  | | --- | --- | | **Field** | **Scan** | | User ID | User ID badge (this is only scanned once for each batch of components) | | Indicator Batch ID | Rad-Sure XR 25 Gy Indicator label Batch ID (Lot number) | | Product Code | Product Code | | Donor ID | Donor Unit Number |   **NOTE:** If data scan does not abide by the format configuration, a red exclamation mark will appear by the field that is incorrect and will be cleared by scanning the correct barcode. Beware that the User ID field is not formatted and will accept incorrect information. | |
| **7** | Select “Add” to populate the chart below the data fields for each unit added to the batch | |
| **8** | Scan all additional units that will be irradiated in one batch (maximum of six whole units, ten for combinations using syringes (six syringes and 4 whole units) | |
| **9** | Review charted units for accuracy and correct any errors   * Click on the **‘Delete’** button at the beginning of the row to remove individual units from the chart * Press on the **‘Reset’** button at the top of the screen o remove all units from the chart | |
| **10** | Return the scanner to the base ensuring it is fully engaged to allow for charging | |
| **11** | |  |  | | --- | --- | | **If Irradiating components in** | **Then** | | Bags | * Carefully insert component bag into the canister * Place canister lid into the slots and lock into place by turning lid clockwise, being careful not to pinch or puncture the product bag | | Syringes | * Place syringe(s) in the syringe holder without pressing the syringe plunger * Use a rubber band to secure the syringe(s) into the holder | | |
| **12** | Press the “DOOR RELEASE” button and pull chamber door handle open to access the canister holders  **NOTE**: Do not let the door swing all the way open on its own, this can damage the hinges | |
| **13** | Slide the loaded canister(s) with the lid facing out /or syringe holder(s) with the syringe plunger out into the canister holder so that the spring returns to its normal resting position.  **NOTE:** Loaded canisters/syringe holders may be placed in any canister configuration, Do not store empty canisters/syringe holders in the chamber | |
| **14** | * GENTLY close the chamber door * Verify Cycle Time is illuminated in the Cycle Time Display | |
| **15** | Press the “START” button- the cycle will start after about 8 seconds and the indicator lights will flash throughout the cycle | |
| **16** | |  |  | | --- | --- | | **If** | **Then the cycle is** | | Buzzer sounds and fault light is not illuminated | Complete   * Go to the next step | | Fault light is illuminated and fault buzzer sounds | * Incomplete * **DO NOT OPEN THE DOOR** * Go to section [Fault Recovery](#fault) | | |
| **17** | Press the “DOOR RELEASE” button and GENTLY pull open door | |
| **18** | Remove all canisters and/or syringe holders carefully and close the chamber door gently | |
| **19** | Remove each component from the canister/holder | |
| **20** | Go to next section | |

**Verifying and Documenting Irradiation**

|  |  |
| --- | --- |
| **STEP** | **ACTION** |
| **1** | Return to RSTScan program and press ‘OK’ on the ‘Cycle Completed’ box |
| **2** | Verify the component was irradiated by confirming the indicator window on the Rad-Sure indicator film is **BLACK**, obscuring the word “NOT” (refer to section ‘Interpretation’) |
| |  |  | | --- | --- | | **If the film is** | **Then** | | Black and the word ‘**NOT’ is obscured** | Check the ‘Indicator Checked OK’ box next to the unit irradiated | | Red and the word ‘**NOT’ is visible** | Do NOT check the ‘Indicator Checked OK’ box next to the unit irradiated | |
| **3** | Repeat step 2 for each component irradiated |
| **4** | Scroll down the screen to verify the indicator check was completed for all components with blackened indicator film |
| **5** | Select the “Save Data” button at the top of the screen and one of the following prompts will appear   |  |  | | --- | --- | | **Prompt** | **Then** | | Cycle completed. Do you want to record? | * Click ‘Yes’ * Go to next step | | Not all indicators checked. Do you still want to record? | |  |  | | --- | --- | | **If the indicator** | **Then click on** | | was reviewed and not acceptable | * ‘Yes’ and the “Cycle completed. Do you want to record?” prompt will reappear * Answer appropriately | | N  eeds to be checked | ‘No’ to return to the main screen and check the box before proceeding | | |
| **6** | Select “OK” when the prompt to the right appears. The chart will reset for the next cycle. |
| **7** | Go to section ‘Results Reporting in Sunquest’ (refer to SOP *Blood Component Preparation)* |

**Fault Recovery**

|  |  |
| --- | --- |
| **STEP** | **ACTION** |
| 1 | **DO NOT OPEN THE DOOR** - Allow 30 sec. to pass after the Fault Light illuminates then press Start Button to restart the cycle  **NOTE:** The fault light will illuminate and the fault buzzer will sound whenever the system detects that any of the internal operations are functioning outside of set parameters |
| 2 | Initiate a QI report to document the event and to keep track of the number of faults in any specific cycle |
| 3 | |  |  | | --- | --- | | If | Then | | 2nd - 3rd fault Restart attempt | **DO NOT OPEN THE DOOR.** Allow 30 sec. to pass after the Fault Light illuminates then press Start Button to Restart the cycle. | | 4th fault | Go to next step | |
| 4 | Open the door and remove all components from chamber. Go to section ‘Results Reporting in Sunquest’ and follow the steps for unacceptable irradiation.  **NOTE**: The cycle is incomplete and the blood components have **NOT** been irradiated to acceptable levels. |
| 5 | Clear the fault by switching the key to “STANDBY” and wait 15 seconds |
| 6 | Turn the key to “CYCLE” and wait 10 seconds |
| 7 | Check to ensure the chamber is empty with no obstruction or other issues and close the door   |  |  | | --- | --- | | **If fault light is** | **Then** | | Off | Press “START” to run a cycle with no blood products | | On | Remove the irradiator from service and contact UW Scientific Instruments or Rad Source for service | |

**Back-up [Irradiation by Radiation Oncology Linear Accelerator](#Linear)**

|  |  |
| --- | --- |
| **STEP** | **ACTION** |
| **1** | * Notify the TSL Medical Director that the RadSource Irradiator is out of service and request APPROVAL to use the linear accelerator * Document the approval on a QI |
| **2** | Notify the Radiation Oncology Dept and TSL Medical Director that the RadSource Irradiator is out of service and irradiation of blood components is needed   |  |  | | --- | --- | | **Time of Day** | **Phone Number** | | Normal business hours  (M-F 8-4:30 pm) | * 8-3997 (physics) * Backup # 8-8246 (therapist) | | Outside of normal business hours | Contact therapist on-call through the hospital operator | |
| **3** | * Place a Rad-Sure indicator label on component to be irradiated without obliterating other required labeling elements * Date and initial the indicator |
| **4** | Record the following on the *Irradiation Downtime Log* for each component   * Date * Rad-Sure indicator   + Lot number   + Expiration Date * Component DIN * Component division (Div.), if applicable |
| **5** | Pack the products in shipping box(s) according to SOP *Packing and Shipping Blood Components* |
| **6** | Take the shipping boxes, Plexiglas case(s) and *Irradiation Downtime Log(s)* to Radiation Oncology (directly across from the Pacific Elevators on the 1st floor). Radiation Oncology staff will direct you to the location of the linear accelerator |
|  | Allow the therapist to warm up and ready the machine before removing the blood components from the shipping containers  **CAUTION:** RBCs should be removed from the shipping box, irradiated and returned to storage in a manner to maintain required temperature. |
| **7** | Place the components in the appropriate Plexiglas for the product being irradiated |
| **8** | Place the box on the linear accelerator allowing the therapist/physicist to position the box correctly and irradiate the components |
| **9** | Record the start time of the cycle in the appropriate field on the *Irradiation Downtime Log* and wait for the cycle to be completed |
| **10** | Give the *Irradiation Downtime Log* to the therapist/physicist to record the following:   * Delivered Central Dose * Signature of therapist/physicist * Date |
| **11** | * Remove the irradiated components from the plexiglass box and place in the appropriate shipping box * Return components to the TSL   **NOTE**: Steps 9 and 10 may be performed in reverse order |
| **12** | * Verify the component was irradiated by confirming the indicator window on the Rad-Sure indicator film is **BLACK**, obscuring the word “NOT” (refer to section [**‘Interpretation’**](#Interpretation)) * Record the result on the ***Downtime Irradiator Log*** |
| **11** | Go to section ‘[Results Reporting in Sunquest’](#Results) (refer to SOP *Blood Component Preparation)* |

**CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL**

**VALUES/CRITICAL VALUES**

**Interpretation**

|  |  |
| --- | --- |
| **Rad-Sure Sticker after irradiation** | **Interpretation** |
|  | Acceptable for transfusion as an Irradiated product |
|  | Unacceptable for transfusion as an Irradiated product |

**Results Reporting**

| **STEP** | **ACTION** | |
| --- | --- | --- |
| 1 | |  |  | | --- | --- | | **If Irradiation is:** | **Then** | | Acceptable | Go to SOP *Blood Component Preparation* for instructions on how to irradiate unit in Sunquest or complete the Irradiation Downtime Log if SQ is not available (Refer to step 6 below for product expiration limits) | | Unacceptable due to any of the following:   * Cycle failure * Rad-Sure Indicator film did not turn **BLACK** and obscure the word **NOT** * Rad-Sure label was not placed on the unit prior to irradiation | Go to the next step | | |
| 2 | Cross out the Rad-Sure sticker with a permanent marker in a manner to not obsure the ability to see the film is still red |  |
| 3 | Open “Blood Product Entry” from Sunquest | |
| 4 | Click ‘Modify Unit’ on the lower left side of the screen | |
| 5 | Scan the unit # and component code in the appropriate fields and click ‘OK’ | |
| 6 | |  |  | | --- | --- | | **If original expiration Date/Time** | **Then** | | >28 days from today | Modify expiration date/time to 28 days from today | | < 28 days from today | Go to next step | | |
| 7 | Click the ‘Comments’ tab at the top of the screen | |
| 8 | Type “**Irradiation Cycle was incomplete**” in the free text field | |
| 9 | Click ‘Add’ then ‘Save’ | |
| 10 | |  |  | | --- | --- | | **If expiration Date/Time was** | **Then** | | **NOT** changed | Return the component to acceptable storage | | Changed | * Reprint the component label * Adhere the label to the component and perform a blood label check (refer to SOP *Blood Component Preparation*) | | |
| 11 | Complete a Quality Improvement (QI) form to document the event See SOP: Occurrence Reporting | |

**CALIBRATION:**

NA

**PROCEDURE NOTES AND LIMITATIONS:**

**Irradiator:**

* The canister must be inserted fully into the canister holder in order for the blood component to be in the proper irradiation field. The canister retaining spring should never be compromised in any way and must ALWAYS be secured.
* Do not place anything in the chamber except for canisters or syringe holders loaded into Canister Holders
* Never interrupt a Cycle once it has been started (except in the event of an emergency). An interruption will result in an incomplete cycle and the blood components will not have been fully irradiated; and therefore, cannot be labeled and issued as irradiated blood components.
* The Chamber Door should be operated gently and never slammed or rapidly opened or closed

**Tablet:**

* If tablet appears to be frozen, it is necessary to restart it. Hold the on/off button until it turns off. After 20 seconds, press the on/off button to turn on the tablet.
* If the tablet enters sleep mode during a cycle, the record of the blood components being irradiated will be erased. Document the cycle on the Irradiation Downtime Log and complete a QI form
* Blood components must be processed in a manner such that time out of controlled storage conditions is limited. Refrigerated blood components must be modified immediately upon completion of the irradiation cycle or returned to monitored storage (in-process shelf) until processing can be completed

**Scanner:**

If scanner fails for any reason, the keyboard can be used to input data. To access keyboard, touch the keyboard icon at the bottom of the screen

**REFERENCES:**

* Technical Manual. Bethesda, MD: AABB Press, current edition
* RS 3400 Operator’s Manual, Rad Source Technologies, Inc. MKT002-09/15, Version 12
* RS 3400 Barcode Scanner Operator’s Manual, Rad Source Technologies, Inc. MKT003-5/15, Version 3
* RS 3400 Syringe Holder Operator’s Manual, Rad Source Technologies, Inc. MKT004-8/15, Version 2

**RELATED DOCUMENTS:**

FORM Irradiation Downtime Log

SOP Blood Component Preparation

|  |  |  |  |
| --- | --- | --- | --- |
| **UWMC SOP Approval:** | | | |
|  |  |  |  |
| **UWMC CLIA Medical Director** |  |  |  |
|  | Mark H. Wener, MD | Date |  |
|  |  |  |  |
| **Transfusion Service Manager** |  | Date |  |
|  | Deanne Stephens |  |  |
|  |  |  |  |
| **Compliance Analyst** |  | Date |  |
|  | Christine Clark |  |  |
| **Transfusion Service**  **Medical Director** |  | Date |  |
|  | Monica Pagano, MD |  |  |
|  |  |  |  |
| **UWMC Biennial Review:** | |  |  |
|  |  |  |  |
|  |  | Date |  |
|  |  |  |  |
|  |  | Date |  |
|  |  |  |  |

3/15/18 – Updating the SOP to include the following changes:

* Changes from manufacturer upgrades
* Clarification of processes
* Updating downtime procedure