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Area	Laboratory-Blood Bank
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The Use of Irradiation Indicators for Irradiating Blood Components - Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide policies and procedures relating to the receipt and use of irradiation indicators when irradiating blood components as described in Transfusion Medicine procedure, Irradiation of Blood Components Using the Rad Source RS 3400 Blood Irradiator.

II. INTRODUCTION:

A. When an irradiation indicator is attached to a blood component, it indicates whether the component has been irradiated; note, however, that it does not indicate the dose received. Before a blood component and its attached indicator have been irradiated, the indicator displays as "NOT IRRADIATED." After the blood component and its attached indicator have been irradiated, a section of the indicator will change color from red to black, which indicates "IRRADIATED."

B. The manufacturer Ashland Specialty Ingredients (ASI) packs a *Temperature History Indicator Card* and Rad-Sure Use Instructions inside each of the boxes within the shipment. All *Temperature History Indicator Cards* and *Use Instructions* must be inspected by a technologist each time a shipment is received and when new box of indicators is opened. The card is reviewed to assess whether proper shipping and storage temperatures have been maintained, and whether the card's instructions for use have been revised

III. SCOPE:

The acceptable irradiation indicators used at Beaumont Hospital- Dearborn are Rad-Sure™ Type 25 Gy X-

ray Indicators.

IV. POLICIES:

A. Receiving Irradiation Indicators

1. When irradiation indicators are received in the Blood Bank, the *Reagent Receipt Log* will be documented as described in Transfusion Medicine Policy, Receipt of Critical Reagents, Materials and Review of Manufacturer's Printed Materials. All the manufacturers' printed materials, including *Temperature History Indicator Cards* for Rad-Sure™ indicators must be reviewed at the time of receipt to confirm that no product revision has occurred.

B. Review of the Rad-Sure™ Use Instructions

1. The manufacturer packs a copy of the Rad-Sure™ *Use Instructions* with each irradiation indicator box of each shipment. The revision date/number of the instructions must be reviewed, to determine whether the instructions have been revised and whether this document needs to be revised accordingly.

C. Review of the Rad-Sure™ Temperature History Indicator Cards

1. All *Temperature History Indicator Cards* must be inspected by a technologist each time a shipment is received and when a new box of indicators is opened, if included. The card is reviewed to assess whether proper shipping and storage temperatures have been maintained, and whether the card's instructions for use have been revised.
2. The color of any *Temperature History Indicator Cards* present should be inspected to verify proper shipping temperatures were maintained.
    a. A black/blue color indicates the proper shipping temperatures were maintained and is considered acceptable.
    b. A red/orange color indicates the proper shipping temperatures were not maintained and is considered unacceptable.
    c. If the *Temperature History Indicator Card appears red/orange in color*
        i. Submit a variance and quarantine the irradiation indicators.
        ii. Notify the Lead Medical Technologist or Supervisor so they can follow up with Ashland Specially Ingredients (ASI).
3. The *Temperature History Indicator Card* present **with each shipment** of Rad-Sure™ indicators should be attached to the *Certificate of Analysis* of the shipment and submitted to the MT Lead or Department Supervisor.
4. The *Temperature History Indicator Card* present **within each box** of Rad-Sure™ Type 25 Gy X-ray Indicators may be discarded once it has been reviewed.

D. Certificate of Analysis

1. Each manufacturer packs a copy of the *Certificate of Analysis* inside the packing box of each shipment. This certificate is submitted to the Lead Medical Technologist or department supervisor. A copy of the Certificate *of Analysis* for each lot number of indicators received will be saved.

E. Shipment and Storage of Irradiation Indicators

1. The Rad-Sure™ Type 25 Gy X-ray Indicators must be shipped and stored to prevent prolonged exposure to direct sunlight and ultraviolet light; and must be kept away from all radiation sources, including gamma rays, x-rays, electron beam devices and microwaves. The indicators must be shipped and stored at appropriate temperature. Therefore, the following policies apply:
2. The *Temperature History Indicator Card* and *Instructions For Use* must be inspected each time a new shipment of indicators is received.
3. Rad-Sure indicators may be kept at 0°C - 25°C. Open boxes are kept by irradiation workstation.
4. All other boxes of Rad-Sure™ indicators of the same lot number and expiration date may be kept in the lower slots of the irradiation workstation if the space permits.

F. Irradiation Indicators Affixed to Each Component before Irradiation

An irradiation indicator should be affixed to each blood component before irradiation.

1. If the component has gone through a complete irradiation cycle, the "NOT" that is clearly visible on the indicator prior to irradiation should now display as "IRRADIATED" after Irradiation.
2. 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.
3. If individual platelet concentrates are irradiated before pooling, then an indicator is affixed to each concentrate.
4. If a large-volume platelet is received in two separate bags but qualifies for irradiation with a volume <500, the indicator shall be affixed to the primary bag only.

G. If the Indicator Does Not Display as "IRRADIATED" after Irradiation

The indicator should display as "IRRADIATED" after irradiation. If the indicator does not display as "IRRADIATED" after irradiation, then:

1. The blood component must be considered partially irradiated. The Partial Irradiation policy will apply, and the product will be labeled with a *Partial Irradiation / Do Not Irradiate tag.*

2. The cause must be investigated and the irradiator shall be taken out of service until the investigation has been satisfactorily resolved.
3. Tag the irradiator with the *Equipment Out of Service Form*.
4. Notify Beaumont Health Biomedical at 248-551-6300 or Rad Source Technologies, Inc. at 678- 765-7900.
5. Submit an internal variance. Refer to Transfusion Medicine Policy, Variance Reporting for additional information.

H. Preventing "Double Irradiation"

1. The presence or absence of an irradiation indicator on a unit is not the only way to determine whether a blood component has previously been irradiated. Components received irradiated from blood suppliers may or may not have an irradiation indicator. Additionally, the indicators could fall off units during handling and storage. The product description on the face label **must** be reviewed prior to affixing the irradiation indicator in an attempt to prevent "double irradiation." This review of the product description is documented on the *Daily Preventative Maintenance, Quality Control, and Irradiation Record of the Rad Source RS 3400 Blood Irradiator*.

I. Emergency Source of Irradiation Indicators

If we run out of irradiation indicators or are likely to run out due to an unacceptable shipment, contact Royal Oak at 1-248-898-9010 or Children's hospital at 1-313-745-5705 to borrow one box of indicators, if needed. Document this information on the *Borrowed/Loaned Reagent Log* and let the Lead Medical Technologist or supervisor know. An internal variance should be submitted. Refer to Transfusion Medicine Policy, Variance Reporting for additional information.

V. QUALITY CONTROL:

1. An irradiation indicator is affixed to each blood product that is to be irradiated. Before irradiation, the indicators should display as "NOT IRRADIATED" and after irradiation the indicators should display as "IRRADIATED" as described throughout this document.
2. For Rad-Sure™ Indicators:
    a. The revision date of the Rad-Sure™ Type 25 Gy X-ray *Use Instructions* must be reviewed when opening a new box of indicators to determine whether the instructions have been revised.
    b. The *Temperature History Indicator Card* must be reviewed when opening a new box of indicators. The card is reviewed to assess whether proper shipping and storage temperatures have been maintained, and whether the card itself has been revised.

VI. Procedure:

A. The Use of Irradiation Indicators for Irradiating Blood Components

1. *The Daily Preventative Maintenance, Quality Control, and Irradiation Record of the Rad Source RS 3400 Blood Irradiator* must be documented and Transfusion Medicine policy, *Irradiation of Blood Components Using the Rad Source RS 3400 Blood Irradiator*, must be followed in conjunction with the following procedure relating to the irradiation indicators.
    a. Obtain enough irradiation indicators to have one for each blood product being irradiated. All indicators being used for an irradiation batch should be the same type (i.e., all Rad-Sure™ or all Rad-Control) and same lot number.
    b. Verify that each irradiation indicator displays as "NOT IRRADIATED."
        i. For all Rad-Sure™ indicators, the word "NOT" is clearly visible in the red window of each indicator, so that the indicator reads "NOT IRRADIATED."
    c. Observe the expiration date of each indicator. If the indicator is beyond the expiration date DO NOT use the indicator.
    d. If using Rad-Sure™ Type 25 Gy X-ray Indicators, document the indicator with the employee's initials and the current date.
    e. Peel an indicator from its backing and affix it near the top of each blood product to be irradiated.
    f. Irradiate the blood products in accordance with Transfusion Medicine procedure, Irradiation of Blood Components Using the Rad Source RS3400 Blood Irradiator.
    g. After irradiation, check each indicator to verify they display as "IRRADIATED."
        i. For all Rad-Sure™ indicators, the word "NOT" is obscured and the window is now black in color.
        ii. If the indicator does not display as "IRRADIATED" after irradiation, then label with product with Partial Irradiation Tag. Refer to the policy, *If the Indicator Does Not Display as "IRRADIATED" after Irradiation.*

VII. REFERENCES:

1. Rad-Sure™ Type XR 15 Gy and Type XR 25 Gy Indicators for X-Ray Irradiation of Blood Products *Use Instructions, rev. Feb 2019.*
2. Ashland Specialty Ingredients *Temperature History Indicator Card.*

Approval Signatures

Step Description	Approver	Date

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