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| **RAD-SURE® Irradiation Indicator** | | | | | |
| **Purpose** | This procedure provides instructions for the quality control and use of RAD-SURE® XR blood irradiation indictors. | | | | |
| **Policy Statements** | A RAD-SURE® XR Irradiation indicator will be used on each individual product being irradiated to show that the blood product has been irradiated. | | | | |
| **Materials** | * RAD-SURE® XR 25 Gy indicators, FDA registration #BK920035 (store at or below 25°C) * PINK QC sticker (RAD-SURE® Binder) * [TSf 17.27.1 RAD-Sure Lot to Lot Card](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/199610.pdf) (Rad-Sure® QC binder) * [TSf 10.8.1 Blood Irradiation Logsheet](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/199557.pdf) | | | | |
| **Quality Control** | Perform a lot to lot comparison with each new shipment of Rad-Sure® indicators.   * Observe color of Temperature History Indicator card. (see step 1 below) * Place one Rad-Sure® from each lot (in-use and new) on a Rad-Sure Lot To Lot card. * Place the QC card in the irradiator canister and irradiate for the posted irradiation time. * Review both indicators confirming that the indicator “window” is black and obscures the word "NOT". The indicator should now read "IRRADIATED" on both new and current lot indicators.  1. Criteria met: Place the QC card in the Rad-Sure® QC binder in the irradiator room and place PINK QC done sticker on all the boxes that came with the shipment. 2. Criteria is NOT met: Quarantine the new lot and notify the technical supervisor or lead immediately. | | | | |
| **Procedure** |  | | | | |
|  | **Step** | Action | | | |
|  | 1 | Observe color of Temperature History Indicator card and document findings on the Blood Irradiation Logsheet.   |  |  | | --- | --- | | **If** | **Then** | | Blue/black | The indicators are safe/OK to use. Proceed to step. 2. | | Red/orange | DO NOT USE indicators. Call 1-855-608-5639 and return box with Temperature History Indicator Card for credit. | | Missing | DO NOT USE indicators. Notify section technical specialist or lead. | | | | |
| Note: Indicators may be kept at room temperature for up to 30 days for ease of use. | 2 | Remove a sheet containing eight Rad-Sure® indicators from the box. Confirm the word “NOT” displays in the window of each indicator. Do not use the indicator unless the word “NOT” is clearly visible. | | | |
| 3 | Bend the sheet to peel an indicator from the backing. Avoid contact of dry adhesive layer with gloves. Apply indicator firmly to clean, dry place on the front of donor unit or syringe barrel prior to irradiation. | | | |
| 4 | Place any remaining indicators back in the box | | | |
| 5 | Date and initial the indicator(s). | | | |
| 6 | Enter or confirm the current lot number of the indicator is documented on top right hand corner of the Irradiator Logsheet. (With each new lot number start a new log sheet.) | | | |
|  | 7 | Irradiate donor unit with attached indicator for the posted time to achieve the recommended dose of 25 Gy (2500 cGy). | | | |
|  | 8 | After irradiation, observe the indicator to verify that the window is black and obscures the word "NOT". The indicator should now read "IRRADIATED" . If the word “NOT” remains visible, notify the technical specialist or lead immediately.  [non irradiated indicator](file:///C:/Users/CE133188/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.IE5/Local%20Settings/Blood%20Bank/pics/Radsure%20Pictures/DSCN1281.JPG)  [irradiated indicator](file:///C:/Users/CE133188/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.IE5/Local%20Settings/Blood%20Bank/pics/Radsure%20Pictures/DSCN1282.JPG) | | | |
|  | 9 | Record the indicator performance on the irradiation logsheet. | | | |
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| **References** | 1. Baldwin ML and Jefferies LC: "Irradiation of Blood Components", AABB, 1992: 63-75 2. Leitman SF, Silberstein L, Fairman RM, Lewis DF: "Use of a Radiation-Sensitive Film Label in the Quality Control of Irradiated Blood Components", Transfusion, 1992: 8S;4S. 3. RAD-SURE® XR Blood Irradiation Indicator Use Instructions product insert, REV: 04:Febuary 2019 | | | | |
| **Approval**  **Workflow** | Transfusion Service/Technical Specialist | | | | |
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| **Historical Record** | **Version** | | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | | Hansen/Wenzel | 2/1996 | Initial Version |
| 2 | | D. Hansen | 8/1997 | New Format |
| 3 | | J. Wenzel | 9/26/2001 | Added 2 cycle information |
| 4 | | Cassidy/Wenzel | 10/20/08 | Lot to Lot QC, New Format |
| 5 | | Sandy Cassidy | 04/10/2012 | Added form numbers. |
|  | 6 | | S. Cassidy | 03/01/21 | Updated for XR Rad-Sure |