TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	4.4.2014
Department:	Blood Bank	**Due Date:**	4.30.2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Quality Control of the Blood Component Irradiator

Description of change(s):

1. Updated Irradiator Log to require more detailed information for daily timer check
    a. Initial irradiator timer setting
    b. Ending irradiator timer setting
    c. Ending reading from verified timer (bench timer)
    d. Interpretation
2. Updated Irradiator Maintenance form to include more detailed information
3. Updated procedure to reflect changes to forms

Quest Diagnostics

Shady Grove Adventist Hospital
Rockville, Maryland 20850

Month/Year: _____

Rad-Sure Lot and Exp. Date: _____

Irradiation Log Sheet

Documentation by Original Tech														Second Tech Review					
Tech	Date	Unit Number (Include Slash Digit for Aliquots)	Pre-Irradiation E Code	Original Expiration Date and Time (if indicated)	Rad-Sure Lot and Exp Date Verified	Canister Rotated?	Timer Check Once per Day of Use (Document "/" When Not Performed)				"NOT" obscured on Indicator?	Time Out of Storage	E Code	Exp Date	Exp Time	Further Processing	Volume	Verified By:
			Post-Irradiation E Code	New Expiration Date and Time (if indicated)	√	Y / N	Initial Timer Setting from Irradiator	Ending Timer Setting from Irradiator	Ending Reading from Verified Timer	Initial Timer & Timer Verification +/- 2s? Y / N	Y / N	Time Returned to Storage	√	√	√	√	√	

AG.F109.001

Reviewed By: _____

Revised 3.27.14

Quest Diagnostics

Shady Grove Adventist Hospital
Rockville, Maryland 20850

Irradiator Maintenance

Monthly Timer Verification	
1. Verify the stopwatch against the US Naval Observatory master clock at 202.762.1401	
Stopwatch Serial Number:	
Stopwatch Start Time:	60 seconds
Stopwatch End Time:	0 seconds
USNO Time Elapsed:	seconds
Interpretation?	Satisfactory or Unsatisfactory (Circle One)
Performing Tech	
Date Performed	
Acceptable Range: Timer and USNO time must match exactly.	
2. Verify the irradiator timer.	
Irradiator Start Time	seconds
Timer Reading	seconds
Interpretation?	Satisfactory or Unsatisfactory (Circle One)
Performing Tech	
Date Performed	
Acceptable Range: Irradiator start time and timer reading must agree within ± 2 seconds	
Quarterly Door Interlock Test	
Does Door Open During Cycle?	Yes or No (Circle One)
Interpretation?	Satisfactory or Unsatisfactory (Circle One)
Performing Tech	
Date Performed	
Acceptable Range: Door does NOT open during cycle	
Quarterly Emergency Power Test	
Is the shield visible?	Yes or No (Circle One)
Can canister be removed?	Yes or No (Circle One)
Drum returns to load/unload position?	Yes or No (Circle One)
Interpretation?	Satisfactory or Unsatisfactory (Circle One)
Performing Tech	
Date Performed	
Acceptable Range: Shield is visible, canister canNOT be removed, drum returns to position	

*****Immediately remove from service is any result is unsatisfactory*****

Reviewed: _____

Electronic Document Control System

Document No.: AG.F.281[0]
Title: Irradiator Maintenance
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 01-May-2014 **Next Review Date:**

Non-Technical SOP

Title	**Quality Control of the Blood Component Irradiator**
Prepared by	Stephanie Codina Date: 10.09.2012
Owner	Stephanie Codina Date: 10.09.2012

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

To provide guidance for routine maintenance and quality control of the IBL 437C irradiator.

2. SCOPE

This procedure applies to the routine maintenance and quality control of the IBL 437C irradiator.

3. RESPONSIBILITY

All blood bank staff must demonstrate competency and comply with this procedure for irradiator maintenance and quality control.

4. DEFINITIONS

N/A

5. PROCEDURE

Calibration

Step	Action
1	Calibration of the irradiator is performed by Pharmalucence A. Annually B. After major repairs C. When the irradiator is installed D. When the irradiator is moved

Form revised 3/31/00

Step	Action
2	The calibration is performed using a fully loaded canister and dosimeter readings are taken at various locations throughout the canister.
3	The irradiator will be removed from service until repairs can be made if the calibration fails.

Quality Control

Step	Action
1	**Each Irradiation Procedure:** Visually verify that the canister is rotating with each irradiation performed. A. If the canister rotates, record "yes" in the "Canister rotated?" column of the Component Irradiation Log Form. B. If the canister does not rotate, remove the irradiator from service and notify a supervisor.
2	**Each Day of Use:** Perform timer checks. A. Obtain a verified timer. B. Record the initial irradiator timer setting on the log sheet. C. Set the timer to the initial irradiator timer setting. D. Begin an irradiation cycle per procedure and simultaneously start the verified bench timer when "Start Cycle" button is pressed (when the orange irradiator light illuminates). E. Stop the bench timer at the same time the irradiator cycle ends. F. Document the ending irradiator timer setting on the log form. G. Document the reading of the verified timer on the log form. H. Interpret the results of the timer verification. a. The time listed on the bench timer should be zero $\pm$ 2 seconds. b. Results are acceptable if the irradiator timer and bench timer agree within 2 seconds. c. Results are unacceptable if the irradiator timer and bench timer do not agree within 2 seconds. Remove the irradiator from service and notify a supervisor if the timer check was not acceptable.

Form revised 3/21/00

Step	Action
3	**Perform Monthly:** Calibrate the irradiator timer. A. Obtain a stopwatch and document the serial number on the QC form. B. Verify the stopwatch by comparing it to the US Naval Observatory (USNO) Master Clock. a. Dial the USNO master clock by dialing 202.762.1401. b. Start the timer. c. Stop the timer at 60 seconds. d. Determine how much time elapsed on the USNO master clock. e. Compare the stopwatch to the master clock. The two must agree exactly to verify the stopwatch. f. Document results and interpretations on the QC form. C. Begin an irradiation cycle per procedure above. D. Start a calibrated stopwatch at the same time the "Start Cycle" button is pressed. E. Stop the stopwatch at the same time the irradiator cycle ends. F. The time listed on the stopwatch should be equal to the start time listed on the irradiator timer. d. Results are acceptable if the irradiator timer and stopwatch agree within 2 seconds. e. Results are unacceptable if the irradiator timer and stopwatch do not agree within 2 seconds. G. Record the results and interpretations on the QC Form. Remove the irradiator from service and notify a supervisor if the timer check was not acceptable.
4	**Perform Quarterly:** Perform the Door Interlock Test A. Start an irradiation cycle. B. Attempt to open the door during the cycle. a. The results are acceptable if the door does not open. b. The results are unacceptable if the door opens. Remove the irradiator from use and notify a supervisor IMMEDIATELY if the Door Interlock Test fails.

Form revised 3.31.00

Step	Action
5	**Perform Quarterly:** Perform the Emergency Power Test A. Start the irradiator cycle. B. Turn the irradiator key to the "off" position during the cycle. C. Open the irradiator door. The shield should be visible. a. The results are successful if you cannot remove the canister. b. The results are unsuccessful if you are able to remove the canister. c. Remove the irradiator from use and notify a supervisor if the test is unacceptable. D. Turn the irradiator to the "on" position. E. Verify that the drum rotates back to the load/unload position after a short delay. a. The test is successful if the drum rotates back to the load/unload position b. The test is unsuccessful if the drum does not return to the load/unload position. c. Complete the entire cycle to reset the timer. F. Notify a supervisor if the Emergency Power Test is unsuccessful.

6. RELATED DOCUMENTS

Form: Irradiation Log Sheet
Form: Irradiator Maintenance

7. REFERENCES

1. IBL 437C - Irradiator Type H Operator's Manual. CIS Bio International.
2. Standards for Blood Banks and Transfusion Services, 29th ed., 2014. AABB Publishing, Bethesda, Maryland.
3. CIS-US, Inc Technical Bulletin TB-001, Quarterly Safety Checks, 9/28/06.
4. Guidance for Industry, Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing, US Department of Health and Human Services, FDA-CBER, Feb 2000.
5. Circular of information for the use of human blood and blood components. Prepared by AABB, the American Red Cross, America's Blood Centers, and the Armed Services Blood Program. Bethesda, MD: AABB, 2009.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
000	3.27.14	Added additional instructions for the monthly timer check for clarity. Updated the forms and references to forms. Updated AABB Standards reference.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

A. Irradiation Time Calculation and Programming

Appendix A

Irradiation Time Calculation and Programming

Time Calculation

1. The IBL 437C irradiator contains Cesium-137 as the radioactive source. Because the energy of the source decays with time, the irradiation cycle time must be periodically re-calculated. The time is calculated annually in December to accommodate decay for the full year to come.
2. Utilize the SGAH Extension of Dose Rate Calibration Tables. Select the Gy • min-1 rate for Dec of the next year (ie, if calculating in Dec 2006, select the Dec 2007 rate).
3. Use the following formula to calculate irradiation time:
   1500 ÷ rate = time in seconds (round up to next whole number)

Program Time

1. On the IBL 437C irradiator keypad, simultaneously press on the 'P' key and the number representing the time (the first numerical figure entered is the most important).
2. Release the 'P' key.
3. Store the time by pressing the 'R' key and then the 'P' key. The new time should now display. (If new time doesn't display, turn irradiator off, then on and time will display)
4. Verify time is correct.
5. Notify blood bank staff that irradiation cycle time has been changed.