



DUKE

DOCUMENT NUMBER: COMM-QA-039 JA1

DOCUMENT TITLE:

Internal Quality Systems Unit Audit Report JA1

DOCUMENT NOTES:

Document Information

Revision: 05

Vault: COMM-QA-rel

Status: Release

Document Type: COMM-QA

Date Information

Creation Date: 13 Jul 2015

Release Date: 07 Jan 2016

Effective Date: 07 Jan 2016

Expiration Date:

Control Information

Author: JPC27

Owner: JPC27

Previous Number: COMM-QA-039 JA1 Rev 04 **Change Number:** COMM-CCR-018

COMM-QA-039 JA1
INTERNAL QUALITY SYSTEMS UNIT AUDIT REPORT JA1
(CONFIDENTIAL)

SECTION I.

The QSU will complete the fields located in Section I.

Program/Facility:	
Number of Observations:	
Composite Audit Score:	
Date of Audit:	

Audit Scope:	
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Background:	
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SECTION II.

Lead Auditor and QSU Director will sign indicating that the observations below in Section III are accurate. Once signed, the report will be distributed to the audited department's representative for completion of Section III.

Lead Auditor's Signature:		Date:
QSU Director's Signature:		Date:

SECTION III.

QSU will complete the Score, Quality System, and Description sections of each observation. The audited department's representative will complete the Person Responsible, Estimated Completion Date, and Response fields and return the form to QSU. The Lead Auditor will then complete the Response Approved Section as appropriate.

Observation #:			
Score:			
Quality System:			
Description:			
Person Responsible:		Estimated Completion Date:	
Response:			
<i>Completed by Lead Auditor</i> Response Approved? <input type="checkbox"/> Yes <input type="checkbox"/> No Initials/Date:			

Observation #			
Score:			
Quality System:			
Description:			
Person Responsible:		Estimated Completion Date:	
Response:			
<i>Completed by Lead Auditor</i> Response Approved? <input type="checkbox"/> Yes <input type="checkbox"/> No Initials/Date:			

SECTION IV. ☐ N/A

For observations labelled Critical or Major, the Lead Auditor will verify that the remediation action(s) described in the response(s) have been implemented and are effective. Otherwise, this section is N/A.

Observation Number	Implemented and effective?	Lead Auditor Initials/Date
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	

SECTION V.

Once the Lead Auditor has approved all the responses and, if necessary, verified the implementation and effectiveness of remediation actions, the Lead Auditor and QSU Director will sign below to close the audit.

Lead Auditor's Signature: _____ Date: _____

QSU Director's Signature: _____ Date: _____

Signature Manifest

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All dates and times are in Eastern Time.

COMM-QA-039 JA1 Internal Quality Systems Unit Audit Report

Author

Name/Signature	Title	Date	Meaning/Reason
John Carpenter (JPC27)		31 Dec 2015, 09:57:08 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		04 Jan 2016, 12:29:50 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Austin Rudisill (ADR35)		04 Jan 2016, 12:51:38 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		04 Jan 2016, 05:55:59 PM	Approved