Frederick National Laboratory for Cancer Research, Frederick, MD

BDP

Biop hannaceutical Development Program

Standard Operating Procedure

Title: Sample Accessioning and Trafficking

SOP Number: 22907

Revision Number: 05

Supersedes: Revision 04

Effective Date: JAN 11 2019

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

Table of Contents

1.0 Purpose

This procedure describes the method for trafficking of samples through the Process Analytics/Quality Control (PA\QC) Laboratory and receiving/ distributingsamples for PA\QC Testing and Inventory by the PA\QC Accessioning Office located in [redacted]

2.0 Scope

This procedure applies to PA\QC personnel who implement the methods for sample trafficking through the PA\QC Laboratories and personnel who receive or distribute QC samples for testing and/or retention.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]

3.0 Authority and Responsibility

3.1 The Manager, Technical Operations, Process Analytics\Quality Control (PA\QC) has the authority to define this procedure.

3.2 PA\QC personnel are responsible for the performance of this procedure.

3.3 PA\QC is responsible for reviewing the data and documentation of the results of this procedure.

3.4 PA\QC is responsible for training laboratory personnel and documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.5 BQA is responsible for quality oversight of this procedure

4.0 Required Documentation

4.1 One of the following documents needs to be submitted to QC Accessioning with the sample(s):

4.1.1 Samples for analytical analysis by QC personnel or off-site vendors require the use of PA\QC Test Request, Form 22002-01. Refer to Section 7 and ***SOP 22002, Request for Quality Control Testing*** for details on this submission process.

4.1.2 Stability samples, Reference Standards, QC retains, or other control materials provided to QC for long-term inventory storage and periodic use will require completing Sample Input, Form 22907-01.

4.2 Products and Samples submitted to PA\QC Inventory for long-term storage

4.2.1 Each entry on Form 22907-01 is logged with the following information:

4.2.1.1 Lot Number

4.2.1.2 Storage Temperature

4.2.1.3 Sample Description

4.2.1.4 Date Received

4.2.1.5 Quantity

4.2.1.6 Freezer Number

4.2.1.7 Rack

4.2.1.8 Location in Box(es)

4.2.2 Attachment 2 shows an example of the Sample Input, Form 22907-01.

4.2.3 Attachment 3 is an example of the PA\QC Test Request Log.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

5.0 Accessioning of Stability and Reference materials

5.1 The requestor submits a Sample Input, Form 22907-01, with Lot number, Storage Temperature, Sample Description, Date, and Quantity entered. The form is to be used to document the submission of reference materials, standards, or other non-clinical lots to PA\QC Accessioning for long-term storage and retention for use as controls.

5.2 Accession personnel assign a Freezer/Refrigerator Number in [redacted] (MEF number for the appropriate temperature regime), Rack, Box, Location within Box, and enters the information in the hard-copy inventory log ([redacted]) and an equivalent entry in the Stability FreezerWorks database.

5.3 Materials that require storage under liquid nitrogen conditions may be stored in MMIC dewars or at the FNLCR Repository under a BDP PA/QC account.

6.0 Sampling Handling for Off-site Vendor Test Submissions

6.1 If an outside vendor is needed for testing, Accessioning personnel must complete the following:

6.1.1 A letter requesting the test ("Release Letter") to the vendor along with the Test Request Form of the vendor, if applicable. The release letter must include PA\QC's Request number, sample(s) and test(s) identity, and BDP's project number for cost center charging. Release letter/Distribution numbers are assigned via the BDP QC Shipment Log located in the [redacted] spreadsheet.

6.1.2 Distribution Record (see ***SOP 22953, Distribution of Process Analytic Samples, Form 22953-01***),

6.1.3 An online submission request through the [redacted] and print a copy of the final shipping form.

6.2 Place samples in proper storage until they are shipped (Documents must be signed by the Director of PA\QC, or designee, before distribution).

6.3 Place samples on dry ice/wet ice or room temperature, as appropriate, for pickup by Safety/ Transportation at the [redacted] loading dock and subsequent shipment to the Contract Lab for testing.

6.4 Test results from the Contract Labs are sent to the Director of PA/QC, designee, or QC Accessioning personnel via email or hard-copy, and data is matched with the QC request for PA\QC and BQA review.

6.5 PA\QC Accessioning personnel complete the QC Test Request form with the vendor test information.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

6.5.1 PA\QC completes Form 22002-01 with the results of test, name of the vendor, and the date the vendor completed their report.

6.5.2 The vendor report and any associated data are printed and attached (or the network location is referenced if vendor files are in an electronic-only format) to Form 22002-01.

6.5.3 The completed QC Test Request report is then submitted for PA\QC review followed by BQA review, per ***SOP 22002, Request for Quality Control Testing***.

6.5.4 Upon QA review and approval, the report is scanned to the Q drive, and the original form and data are returned to BQA for archiving per ***SOP 22009 - Quality Control Test Request Scanning, Verification, and Adobe File Archiving.***

7.0 Sampling Trafficking through the PA\QC Laboratory

7.1 The sample is brought to the PA\QC lab by the requestor; the PA\QC Test Request (Form 22002-01) must be electronically filled out completely and accurately **– NO HAND-WRITTEN FORMS WILL BE ACCEPTED.** Only one analysis is to be requested per form, though multiple samples (for the same, single assay for the same project) are permitted. QC Accessioning or QC personnel review the samples submitted, checks the form for inaccuracies and omissions, signs and dates (with time of receipt) and indicates the location of the samples.

7.2 A photocopy of the QC test request marked “file copy” is used to enter the QC request into the PA/QC Accessioning database and is subsequently placed in the PA\QC Accessioning office files until the test request is complete and scanned. Samples are labeled with the QC test request number (where feasible), placed in a plastic bag or container labeled with the QC number, and stored at the appropriate temperature until analysis. QC test request forms are placed in analyst folders in the Accessioning office [redacted]) for pick-up and subsequent PA\QC analysis.

7.3 When necessary, QC samples can be aliquoted or shared by BDP personnel for each test requested.

7.4 QC test request (QCTR) forms and the PA\QC request logbook are filled out by BDP personnel for all QC test requests. For off-site testing, PA\QC Accessioning personnel will assign a sequential release letter number using the release letter log and generate a vendor Release Letter to the on-post (i.e. non-BDP labs at FNLCR) or contract/outside lab requesting the test. Refer to Section 6 for details.

7.5 Following sample shipment, PA\QC Test Request Forms are placed in the Accessioning QCTR file along with the associated vendor forms (protocols, etc.) and FNLCR shipping documentation until the test report is received.

7.5.1 When the Release Letter has been signed by the Director, PA\QC, or designee, samples are delivered by FNLCR Transportation to either on-post (i.e. non-BDP FNLCR) labs or outside vendors via courier or FedEx.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

7.5.2 A note is made in the PA\QC Release Letter log indicating when the samples were sent.

7.5.3 Receiving labs or vendors should sign and date the PA\QC Sample Distribution, Form 22953-01, sent with each shipment, indicating their receipt of the sample and provide the original (or a copy) to PA\QC. Emailed or faxed copies are acceptable. Some vendors will provide their own sample receipt documentation in lieu of completing Form 22953-01.

7.6 Test results and reports are returned from vendor as hard-copies or via email to the QC Director or Accessioning personnel. Following receipt of all vendor documentation the reports are handled per Section 6.4.

7.7 If the vendor's results are not within assigned specifications, then an Out-of-Specification (OOS) (***SOP 22004, Investigating Out-of-Specification Test Results or Unexplained Discrepancies***) investigation is initiated by PA\QC (see Attachment 1). In conjunction with the BDP OOS investigation, the off-site vendor must also be contacted to have them initiate a procedural review and OOS investigation at BDP request.

8.0 References and Related Documents

8.1 **BDP SOP 22002** *Request for Quality Control Testing*

8.2 **BDP SOP 22004** *Managing Out-of-Specification Test Results or Unexplained Discrepancies*

8.3 **BDP SOP 22953** *Distribution of QC Samples*

8.4 List all other non BDP references.

9.0 Attachments

9.1 Attachment 1 PA\QC Sample Accessioning and Tracking Flow Chart

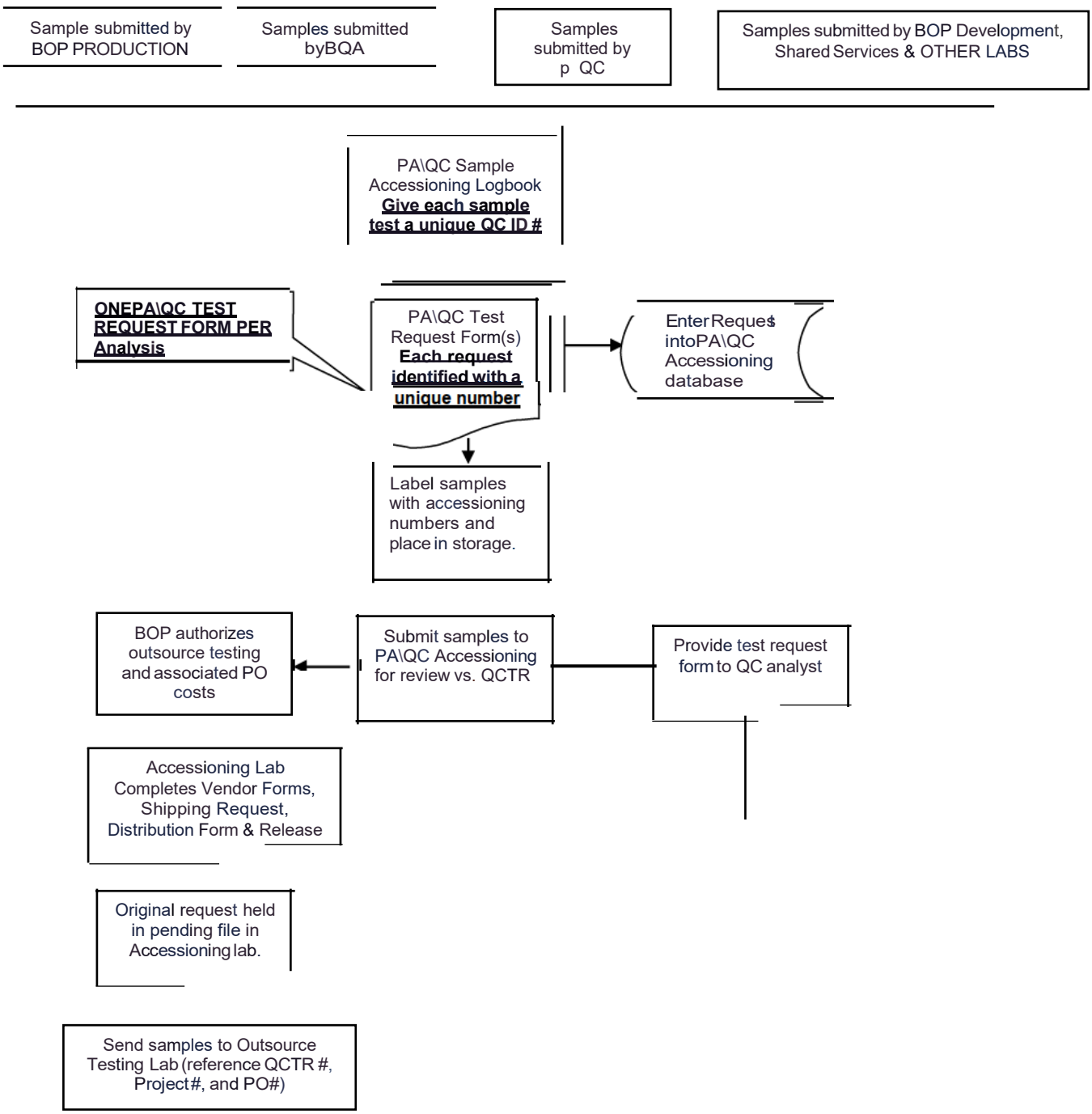
9.2 Attachment 2 Sample Input, Form 22907-01

9.3 Attachment 3 Sample of PA\QC Test Request Log

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

Attachment 1

PA\QC Analytical Sample Accessioning and Tracking Flow Chart



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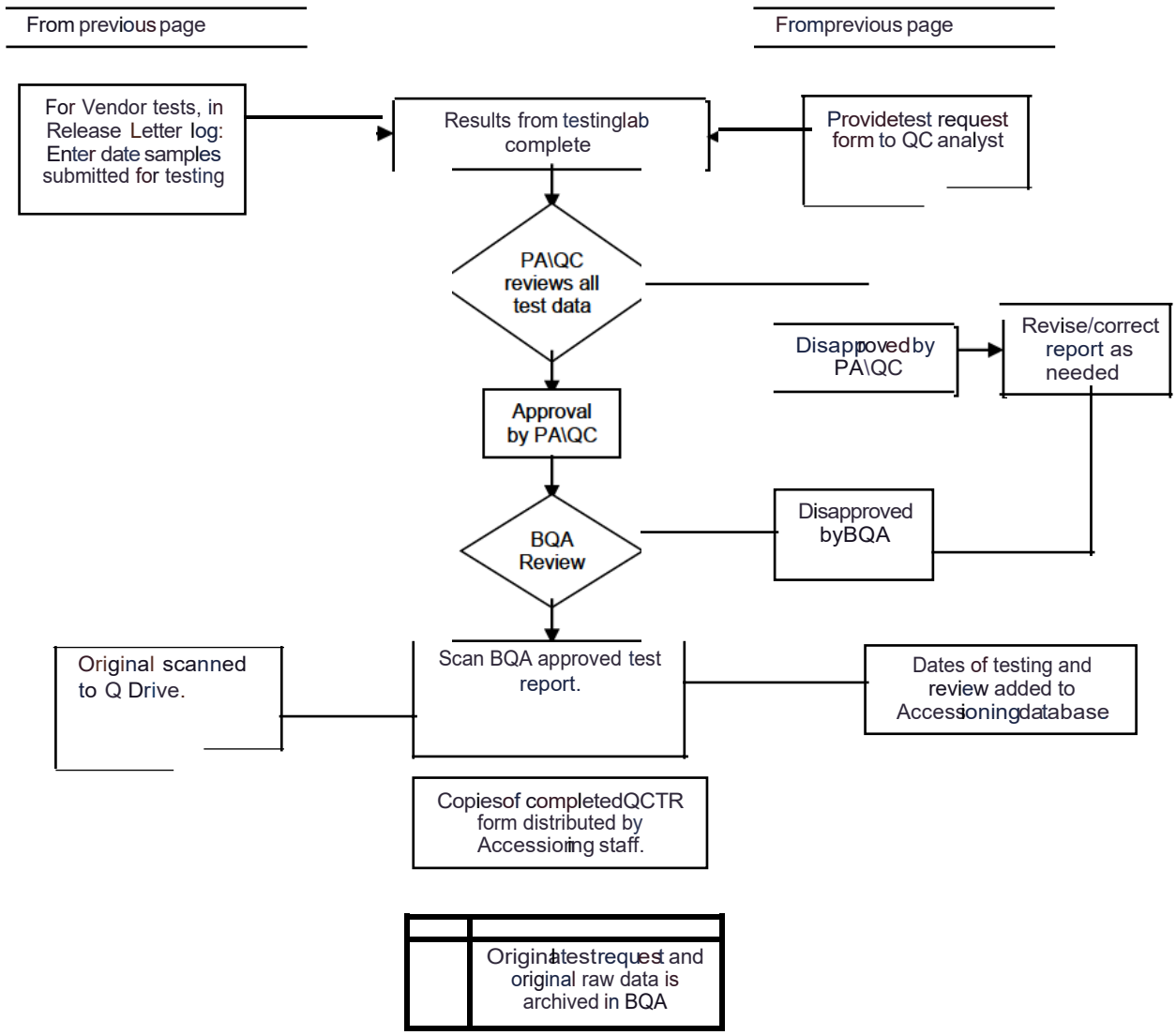
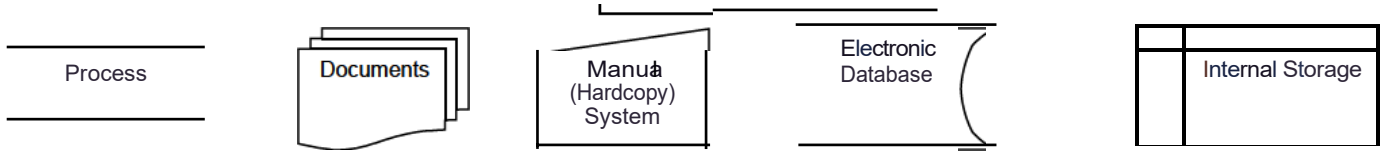
Attachment 1 (continued)

PA\QC Sample Accessioning and Tracking Flow Chart



KEY TO FLOW CHART SYMBOLS



This procedure is made available throughfederal funds from the NationalCancer Institute, NIH, under contract [redacted]

Attachment 2

NCI-Frederick
Form No: 22907-01
SOP No.: 22907
Revision 05:

This is not the actual size of the form.

FNLCR, BOP
Form No.: 22907-01
SOP No.: 22907
Red sion 05: JAN 11 2019

SAMPLE INPUT

Sample input lnfo nn atio n (Co mp leted by Requ es ter)

Lot Number: _____ Storage Tcmperarure: _____

Sam p le De sc rip tio n: _____

Received _____ u t i t __

atilfiq Analytics)

Fereze r Nun1ber_____ Rk. _____

B _____

ainBox _____

Box _____ Rack_____

Loi i t _____

Box _____ Rack _____

Loction in Box _____

t Bt _____

RBt: _____

[redacted]

This procedure is made available through federal funds from the National Cance Institute, NIH, under contract [redacted]

Attachment 3

Sample of PA\QC Test Request Log

Below is a typed example of what is handwritten in the PA\QC Test Request Log.

QC#	Requestor	Date	Sample Name	Lot #	Assay Name	# Samples	Storage Temp.	QC Analyst	Picked Up	Completed By Analyst

NOTE: This is the logbook, not the PA\QC Test Request Form.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]