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1.0 Purpose

This SOP describes the controls, processes, and documentation required for distribution of documents by the Biopharmaceutical Development Program (BDP) to external recipients and institutions.

2.0 Scope

The procedure applies to BDP employees who control, process, and record the distribution of documents. This procedure encompasses documents and other media generated by the BDP that are provided to external recipients. The procedure does not apply to documents sent between the BDP and the Biological Research Branch (BRB). A distribution form for documents is not required if sending project related documents to current US government customers.

3.0 Authority and Responsibility

- 3.1 The Director, Regulatory compliance/ Quality Assurance has the authority to define this procedure.
- 3.2 All distribution requests must be approved by BQA/Process Analytics/Quality Control (PA/QC) and the National Cancer Institute (NCI)/BRB or their appointed designees.
 - 3.2.1 PA/QC approves the distribution of documents associated with analytical testing, stability, and other study activities.
 - 3.2.2 BQA approves the distribution of all other documents.
- 3.3 The requestor is responsible for completing the Distribution Record form, as well as the Request for Shipment form, if required.
- 3.4 BQA administrative personnel (or designee) are responsible for obtaining approval from BQA/PA/QC and NCI/BRB prior to distribution and processing of controlled documents.



- 3.5 BQA administrative personnel (or designee) are responsible for maintaining copies of the approved Distribution of Records and Request for Shipment in the project or general distribution files.
- 3.6 It is the responsibility of the requestor to forward a copy of delivery receipt to BQA administrative personnel.
- 3.7 It is the responsibility of the requestor to notify BQA if a shipment is cancelled.
- 3.8 BQA is responsible for the implementation of this procedure.

4.0 Procedure

4.1 Distribution Record for Documents Form

- 4.1.1 The requestor electronically completes the online Distribution Record for Documents, Section A (Form 21417-01 – Attachment I) and the EHS Shipping form (if required; See Section 4.2).

NOTE: Handwritten Distribution Records are not acceptable.

- 4.1.2 The requestor attaches the distribution record, signed shipping form (if required), a copy of the request for the document (i.e., email from PI) and any other necessary documents to the email and sends it to the BQAD Outlook Mailbox. Controlled documents need to be requested from BQAD to ensure the signatures are redacted (when appropriate) and the proper warning statement is applied (like "uncontrolled copy - for training purposes only).
- 4.1.3 The following information on the distribution record should be completed for BQA administrative personnel (or designee) to assign a distribution number.
 - The type of document being sent.
 - Cost Center No. - **** NOTE:** This section can be marked N/A if document(s) are being distributed via secure upload or email since there are no shipping costs.
 - Project Number
 - Project Name
 - Complete Description of Document(s) – detailed information, (not just SOP or MS, COA) and reason for shipment. If SOP include the SOP number and title
 - Shipping Method – FedEx, Email, SEFT
 - Recipient Name, phone number, and email the package is being sent to.
 - **Facility and address the package is being sent to.**
 - Requested by and the Date, On Behalf of.
 - Copy of the email or document requesting the distribution of the document(s).

- 4.1.4 BQA Administrative personnel (or designee) assigns a distribution number and completes the required information in the Distribution Request Log located in

4.1.5 BQA Administrative personnel (or designee) add the distribution number to the distribution record and routes for e-approval.

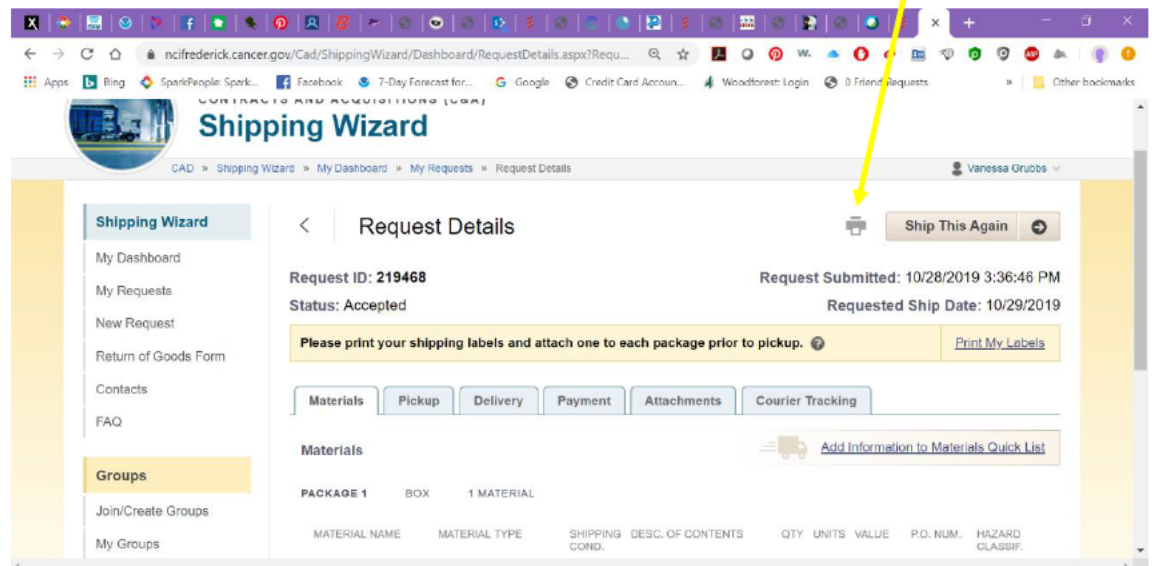
4.2 Request for Shipment Form

4.2.1 The Request for Shipment form is located at

<https://ncifrederick.cancer.gov/Cad/ShippingWizard/Groups/GroupDashboard.aspx?GroupId=8d88e112-f02d-4978-9847-8397a47cb335>

NOTE: A Request for Shipment form is only required for physical shipments and is not required for documents sent by email, fax, or via the internet.

4.2.2 The Request for Shipment form is an intuitive online form that will guide the requestor through the process for filling out the form. Once submitted, you will receive an email that contains the Request ID number. Click on the ID number link, which takes you back to the shipping website. Click on the printer icon beside the "Ship This Again" button and print as a pdf document of the shipping document. Include this pdf document in the email to BQAD.



4.2.3 BQA Administrative personnel (or designee) prints the distribution record, approved shipping form (if required), the request for distribution, and obtains approvals from BQA/PA/QC and the NCI/BRB.

4.2.4 Once all approvals are obtained, BQA Administrative personnel (or designee) makes a copy of the entire package and files it in the project files in BQA document room.

4.2.5 BQA personnel (or designee) will fax the Request for Shipment form to Transportation at Ext. 6971, if applicable.

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- 4.2.6 A copy of the approved Distribution Record form is to be packaged with the documents as it is this form that the recipient is to fax back to BQA (301-846-1438).
 - 4.2.7 If the document(s) are not to be shipped via Federal Express, place them in the appropriately sized envelope, affix the label and attach the approved Request for Shipment form to the outside of the package. If the documents are to be shipped via Federal Express, place the documents together with the distribution record and shipping form.
 - 4.2.8 The final package will be put in the outgoing mail bin located on the first floor [REDACTED] behind the Security Desk.
 - 4.2.9 If documents are being distributed via email or fax, a scanned copy of the Distribution Record should be included with instructions to the recipient to complete Section C and return via email or fax.
 - 4.2.10 Confirmation of Delivery Receipts
 - 4.2.10.1 Delivery confirmations received by the requestors should be forwarded to BQA to be filed in the project file. Receipt number should correspond to the document request number. Delivery confirmation may be in the form of an email from Federal Express, the Transportation department, by return fax from the recipient, read or delivery receipt, or note to file that verbal confirmation has been received from the recipient
 - 4.2.10.2 Once delivery receipt is confirmed, BQA personnel (or designee) should update the Distribution Request Log with the receipt information and placed a copy of the receipt distribution record (if received) in the project file with the original package.

5.0 Definitions

- 5.1 **External Recipients** – Any individual/group outside of the BDP and the BRB (i.e. CTEP, DTP, DCTD, NIAID, VCMP, etc.).
- 5.2 **Other Media** – Including, but not limited to, CDs, binders, etc. by which written documents are provided.
- 5.3 **Types of Distribution** – Email, fax, physical shipment, posting to the website and hyperlinks created by IT.



6.0 Change Summary

