

Finalization of Facility Documents

This document is to give direction to the Biologics Compliance Assistant (BCA) to finalize facility documents and the additional documents that the Specialist has provided. (NOTE: The work instruction that the Specialists use is **ICWI0083**, *Facility Documents: Specialist Review and Outgoing Correspondence*.)

I. Hard Copy Submissions

The Specialist will return all facility documents and hard copy of the FDS form signed (not dated) back to the BCA. The BCA can re-verify that all facility documents are as stated on the FDS form and the boxes have been checked.

A. Documents Filed

1. Date stamp the FDS form the same date as the facility documents are stamped
2. Ensure the Specialist has marked the correct box on the FDS form in Block 9, CVB Action, as **Documents Filed**
3. Verify the Specialist signed the FDS form
4. Date stamp the facility documents that have been approved by the Specialist with the USDA stamp in bottom right-hand corner of document
5. Scan the signed and dated FDS form and attach as *Outgoing General Correspondence*
6. Make a copy of FDS form for CVB files
7. Add Notifications
8. When all documents have been attached and the Submission Response has been filled out, **ensure tag for Suppress Response From Portal has been done**
9. Move Mail Log item to the Specialist as *Sign Correspondence (IC)*
10. Give the purple folder to the Specialist to “sign” and move onto Section Leader

B. Documents Filed, Revisions Requested

1. Date stamp the FDS form the same date as the facility documents are stamped
2. Ensure the Specialist has marked the correct box on the FDS form in Block 9, CVB Action, as **Documents Filed, Revisions Requested**
3. Verify the Specialist signed the FDS form
4. Date stamp the facility documents that have been approved by the Specialist with the USDA stamp
5. Scan the signed and dated FDS form and attach as *Outgoing General Correspondence*
6. Make a copy of FDS form for CVB files
7. Add Notifications
8. Finalize the **ICTEM0045**, Facility Documents Filed – Revisions Requested (no legend line is needed on this document, just the ML#)
9. Pdf the document and attach as *Outgoing Enclosures*

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Establishment Name, Est. Number
Site of Submission

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Facility Documents Filed – Revisions Requested

Review VS Memorandum 800.78, Preparation and Submission of Facilities Documents for established practices related to preparing facility documents. Address all revisions requested and ensure the submission has been reviewed by personnel familiar with the regulations and guidance documents prior to resubmission. |

Addendum – Decontamination Procedures – Building 1, Page 5

1. Lysol is listed as a disinfectant. Please also include the generic, non-trade name of the disinfectant.

[Reference: 9 CFR 108.5(b)1]

Addendum – Decontamination Procedures – Building #3, #3B, #3C Page 8

2. Spectrasol and Oxivir are listed as disinfectants. Please also include the generic, non-trade name of the disinfectant.

[Reference: 9 CFR 108.5(b)1]

10. When all documents have been attached and the *Submission Response* has been filled out, **ensure tag for Suppress Response From Portal has been done**
11. Move Mail Log item to the Specialist as *Sign Correspondence (IC)*
12. Give the purple folder to the Specialist to “sign” and move onto Section Leader

C. Documents Returned

1. Date stamp the FDS form the same date as the facility documents are returned
2. Ensure the Specialist has marked the correct box on the FDS form in Block 9, CVB Action, as **Documents Returned**
3. Verify the Specialist signed the FDS form
4. Scan the signed and dated FDS form and attach as *Outgoing General Correspondence*
5. Make a copy of FDS form for CVB files
6. Add Notifications
7. Finalize the **ICTEM0045**, Facility Documents Returned - Resubmit with Corrections by *[date]* (no legend line is needed on this document, just the ML#)
8. Pdf the document and attach as *Outgoing Enclosures*

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Establishment Name, Est. Number
Site of Submission

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Facility Documents Returned – Resubmit with Corrections by [date]

This submission was not adequate or complete and did not meet the regulations cited in 9 CFR Part 108. Review VS Memorandum 800.78, Preparation and Submission of Facilities Documents, for established practices related to preparing facility documents. All corrections required may not be listed, therefore prior to the next submission, personnel familiar with the regulations and guidance documents must review the documents for sufficiency.

TYPE OF DOCUMENT – Document identity

1. List issue that is not in compliance
[Reference: 9 CFR 108.XX]

TYPE OF DOCUMENT – Document identity

2. List issue that is not in compliance
[Reference: 9 CFR 108.XX]

9. When all documents have been attached and the Submission Response has been filled out, **ensure tag for *Suppress Response from Portal* has been done**
10. Move Mail Log item to the Specialist as *Sign Correspondence (IC)*
11. Give the purple folder to the Specialist to “sign” and move onto Section Leader.

NOTE – only one **ICTEM0045** is required per ML submission. It may have both Revisions Requested and Documents Returned.

Facility documents and additional documents will be returned to the firm as Certified Mail. The Section Leader should return the Mail Log to the BCA as Certified Receipt.

II. Electronic Submissions

A. Documents Filed

1. No “Outgoing General Corr” is needed
2. Open the IC Clean Copy type for each document
3. Ensure the appropriate stamp is applied



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4. Ensure there is a DATE under the stamp. It should be close to the date of Review (Specialist)
5. Review nomenclature for each document – see **ICWI0083**, Section V and VII.C
6. If correct, upload all documents as “Outgoing Enclosure” (Do not upload any Summary of Changes)
7. Add Notifications
8. Complete *Submission Response* under Info tab
9. Move Mail Log item to the Specialist as *Sign Correspondence (IC)*

B. Documents Filed, Revisions Requested

1. Finalize **ICTEM0049** for the Specialist’s digital signature
2. Attach pdf copy of **ICTEM0049** as “Outgoing General Corr”
3. Open the IC Clean Copy type for each document
4. Ensure the appropriate stamp is applied



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5. Ensure there is a DATE under the stamp. It should be close to the date of Review (Specialist)
6. Review nomenclature for each document – see **ICWI0083**, Section V and VII.C
7. If correct, upload all documents as “Outgoing Enclosure” (Do not upload any Summary of Changes)
8. Add Notifications
9. Complete *Submission Response* under Info tab
10. Move Mail Log item to the Specialist as *Sign Correspondence (IC)*

C. Documents Returned

1. Finalize **ICTEM0049** for the Specialist’s digital signature
2. Attach pdf copy of **ICTEM0049** as “Outgoing General Corr”
3. Ensure there are no outgoing enclosures
4. Add Notifications
5. Complete *Submission Response* under Info tab
6. Move Mail Log item to the Specialist as *Sign Correspondence (IC)*

NOTE – Under the Documents tab, there should only be the incoming attachment(s), a Clean Copy for each document filed, and outgoing enclosure(s) and/or 1 outgoing correspondence.