

Inspection Tools – Requested Documents and Observations

REQUESTED DOCUMENTS - ICFRM0027

It is customary to request numerous documents for review during an on-site inspection. Form ICFRM0027, *Inspection, Requested Documents Worksheet*, facilitates tracking what documents have been requested, received, and reviewed. This worksheet is considered part of the inspections notes. Each team member's ICFRM0027 will be attached to the Mail Log for the inspection report and can be used to prepare subsequent inspections for the site.

PROCESSES OBSERVATIONS – ICFRM0026

During the on-site inspection, the inspectors may observe the firm performing various steps of production. ICFRM0026, *Inspection, Processes Observed Worksheet*, facilitates documenting these observations. This worksheet is considered part of the inspection notes. Each team member's ICFRM0026 will be attached to the Mail Log for the inspection report and can be used to prepare subsequent inspections for the site.

These forms can be either hand-written or electronic (pdf fillable form). If electronic, please print and add to handwritten notes. If hand-written, scan and add to Mail Log.

Guidelines for each document:

1. Inspection, Requested Documents Worksheet – ICFRM0027

INSPECTION
Requested Document Worksheet

Team Member: _____ Est. #: _____ Page: _____ of _____

| Rqst Date | Rcv'd Date | Document Name | Doc ID# | P. Code/ Fraction | Serial/ Lot # | Room # | Pg # (review) | Reviewed |
|--------------|---------------|---------------|---------|----------------------|------------------|--------|------------------|--------------------------|
| | | | | | | | | <input type="checkbox"/> |
| | | | | | | | | <input type="checkbox"/> |

Each field may or may not be applicable to the specified request. If not applicable, mark the field as NA. If an item does not relate to one of the below fields, use the next best associated field.

- a. Rqst Date – Date the inspector requested the document from the firm
- b. Rcv'd Date – Date the inspector received the requested document from the firm
- c. Document name – General term for the request or Specific Document Name (i.e., Testing Bench Records or Egg Accountability and Use Record)

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- d. Document ID – If the firm has a specific name (ID #) for the document (i.e., ICFRM0027)
- e. P. Code/Fraction – Specify the product code, if finished product, or fraction if bulk lots or Seeds/Cell records
- f. Serial/Lot # - Specify the Serial # if finished product, or Lot # if bulk lots or Seeds/Cell records
- g. Room # - if records pertain to specific rooms, such as cleaning records or autoclave records, document the room and building.
- h. Pg # (review) – for reference to inspector’s notes that document review – suggest using the date of the notes and then the page number. For example, 9/23, 4 represents notes taken on Sept. 23rd, listed on page 4.
- i. Toggle box – to indicate review complete

2. Inspection, Processes Observed Worksheet – ICFRM0026

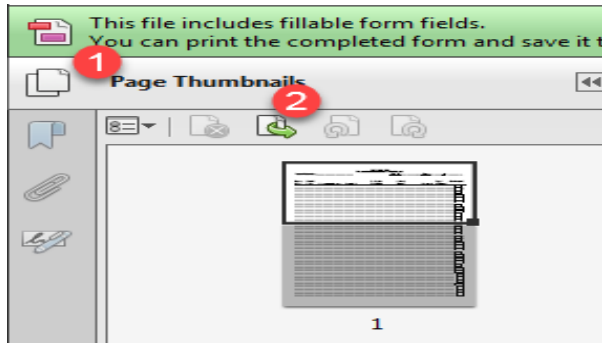
INSPECTION
Processes Observed Worksheet

Team Member: _____ Est. #: _____ Page: _____ of _____

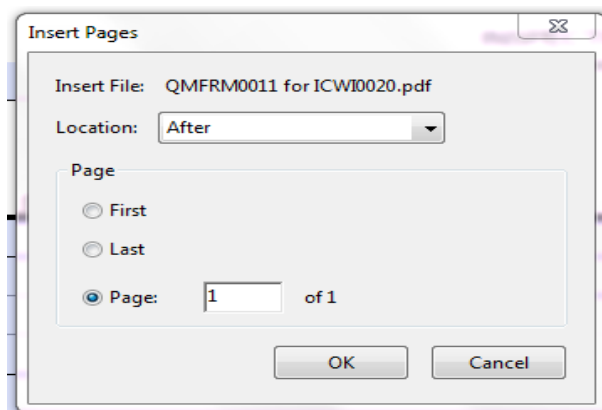
| Date | Process Observed | P. Code/Fraction | Serial/Lot # | Room # | Pg #(review) |
|------|------------------|------------------|--------------|--------|--------------|
| | | | | | |
| | | | | | |

- a. Date – Date of the observation
 - b. Process Observed – specify the production step (i.e., filling)
 - c. P. Code/Fraction – specify the applicable product code for final product, or fraction for bulk or seed/cell production step
 - d. Serial/Lot # - Specify the Serial # if finished product, or Lot # if bulk lots or Seeds/Cell records
 - e. Room # - Specify the room and building # for where the production step occurred
 - f. Pg # (review) – Specify the pages of applicable note pages where the inspector’s observations are documented. Suggest using the date of the notes and then the page number. For example, 23/4 represents notes taken on the 23rd, listed on page 4.
3. If you utilize the electronic version of these documents and create more than one page during the inspection, you can merge the two documents by the following steps:
- a. Save each page separate
 - b. Open the left hand tab – “Page Thumbnails”
 - c. Choose the icon – “Insert page from another file”

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- d. Select the file you saved previously – then choose “Open”
- e. You will be asked where to insert the page – choose the location and click OK



- f. Resave.