Redaction Process for Inspection and Compliance Documents Posted to the CVB Website – Inspection and Compliance Manual

This document outlines the redaction process for Inspection and Compliance (IC) documents posted to the CVB Website in the Inspection and Compliance Manual. This process applies to IC documents managed by CVB Quality Management (QM).

After the document has been released in the CVB Quality Management (QM) system, the QM Program Assistant:

- 1. Under the appropriate section(s), links the document in the IC Manual located on the CVB QM SharePoint site. (The document author decides under which section(s) the document is to be linked.)
- 2. Enters the IC Manual section number in the QMS Document Tracking Spreadsheet (located on the CVB QM SharePoint site) under the "Website" column.
- **3.** If IC Management requests that a document **not** be posted to the CVB Website, note that in the QMS Document Tracking Spreadsheet under the "Website" column. **Note:** IC templates are not posted on the CVB Website.

The QM Program Assistant enters the document into the LSRTIS Mail Log under Create Mail Item for forwarding to the IC Director:

1. Create Mail Item:

- a. Select Category: IC
- b. Establishment: NA
- c. Date Submitted: current date
- d. Date Received: current date
- e. Submission Type: Internal Projects IC
- f. Submission Subtype: QM Document, click "Add"
- g. Brief Description: redaction requested for posting to CVB Website, IC Manual, document number(s), and section(s).Note: If you are requesting that multiple documents be redacted, you can include them all in one request.
- h. Click "Create"

Create Mail Item					
Select Category	. C				
Establishment	NA				
Product	O Add				
VBI Number					
Date Submitted	11/02/2016				
Date Received	11/02/2016				
Submission Type	Internal Projects - IC				
Submission Subtypes	Add • QM Document	×			
Regulatory Action Source					
9CFR Violations	QSearch & Select				
Tags	Add				
Brief Description	Please redact ICWI0063.02 for posting to CVB Website in IC Manual, Section 18.5				

ICWI0043.02

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Source Document: PIMSSOP0108, External Distribution of Quality Management Documents for the Center for Veterinary Biologics; PIMSSOP0006, Initiating and Processing CVB Website Change Requests

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2. Create attachment in LSRTIS

(*Upload the document(s) that are to be redacted*)

- a. Select file to upload (PDF of the document)
- b. Type: IC Manual
- c. Comments: for redaction or can leave blank

d. Click on "Save and Add another Document" or "Save and Return to Item Record"

MailLog # 182620	Establishment NA	Product Code	Brief Description Please redact ICWI0063.02 for posting to CVB Website in IC Manual, Section 18.5	Type Date Submitted Internal Projects - IC November 02, 2010
Mail Item 1	82,620 created			
Select File Lo	cation	Uploade	d File ◯ Hard Copy	
Select File to	Upload	K:\QA\QM S	Section\Documents\WIs\IC\ICWI0063.02.pdf Browse	
Гуре *		IC Manua		
Tags			+Add	
Comments		for redact	ion	

3. Move Item Forward (to IC Director)

- a. Director's Review/Approval
- b. Assigned Individual -Karli, Steven
- c. Click on "Move Item"

Move Item							
MailLog # 182620	Establishment NA	Type Internal Projects - IC	Queue Entry Date November 2, 2016 7:27 AM	Reason Initial Entry - IC			
Director's Revie	w/Approval	V	Routing Comment:	\$			
Assigned Inc Ocoyle, Danie Karli, Steven Oschnurr, Rer	dividual(s) ee		✓ Move Item				

4. The document is reviewed and redacted by the IC Director who then forwards the redacted document through the LSRTIS Mail Log to the QM Program Assistant.

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- 5. Upon receipt of the redacted document, the OM Program Assistant saves the document to the QMS Electronic Document file located on the local network . The redacted drive, document is identified as: document alphanumeric redacted (example: ICWI0048.01 redacted).
- 6. If the document has not been previously posted on the CVB Website, PIMSFRM1108, Document Publication Form, must be completed prior to initiating a Website Change Request through the LSRTIS Mail Log. (If the document is already posted on the website, the form does not need to be completed again).
- 7. Following the process outlined in **PIMSSOP0006**, *Initiating and Processing CVB* Website Change Requests, the QM Program Assistant initiates the Website Change Request for posting of the redacted document to the CVB Website.
- 8. After verifying the document has been posted to the CVB Website, the QM Program Assistant moves the Mail Log item forward:
 - a) Move Forward
 - b) Workflow completed No records management
- 9. The hard copy of the **PIMSFRM1108** is filed in the document's folder located in the Master Document Files.