

Inspection Report – Closing Action Items in LSRTIS

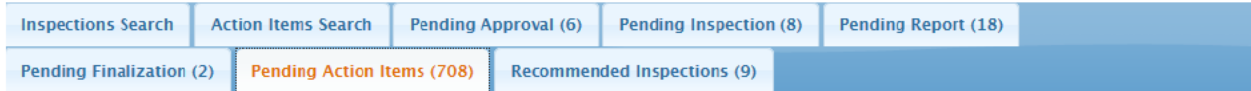
Action items are entered into LSRTIS prior to finalization of the inspection report. In most cases, the regulated entity will submit a letter indicating if the action has been resolved and how. Review of these letters should lead to the closure of action items in LSRTIS. There is also an opportunity to document notes related to the action item and responses that can be reviewed on the next inspection.

Depending on what data you are going to save for the action items, there are two ways to close an action item.

I. CLOSING ACTION ITEMS WITHOUT NOTES FOR NEXT INSPECTION

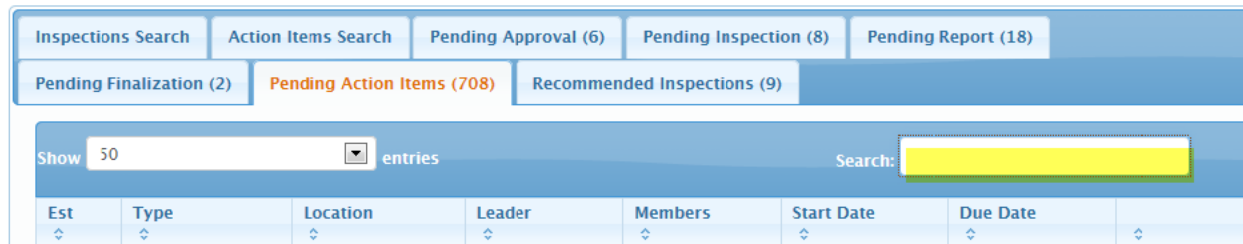
This method is used when several action items are closed at the same time with the same response.

1. Go to Inspections Dashboard – Tab Pending Action Items




2. Put the Est. number in the Search field (yellow box)

Inspections Dashboard



3. This will list the open action items for an establishment, but please note it may have several locations listed. Using the information in the screen, chose the correct inspection, and click on “Inspection” right side of screen.

Est	Type	Location	Leader	Members	Start Date	Due Date	
[REDACTED]		Wonderlich, Norman	Wonderlich, Norman, Couture, Laurier		04/28/2014	08/01/2014	Inspection
[REDACTED]		Yearly, Teresa	Yearly, Teresa, Wonderlich, Norman		03/24/2014	05/23/2014	Inspection 
			Yearly, Teresa,				

(Clicking on Inspection by the green arrow will open the action items for the in-depth inspection at De Soto for Est. 165A, not the follow up inspection at Millsboro.)

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4. Scroll down to Action Items. Find the action item you want to close and click on box on left. You may choose to close multiple action items at the same time – please note they will all have the same completion comments and completion date.

Action Items

Info

Category	Priority	Violation	Action Item Due Date	Completion Date	Info
EQUIPMENT	SERIOUS	113.26			

Observations

Observation

Temperature records for incubators [REDACTED] located in the lower level of the Building [REDACTED] indicated that automatic temperature downloads from the [REDACTED] stopped sometime in [REDACTED]. Temperature data was available beginning in [REDACTED]. At the time of the inspection the firm could not retrieve any temperature data from [REDACTED]. These incubators were used for the incubation of purity (sterility) testing for serial release testing. We expressed our concern that tests completed during the time there was no temperature data stored could have been invalid due to temperature deviations. [REDACTED] agreed to provide to the CVB information regarding the firm's investigation into this problem. Included in the response should be assurances from the firm that the tests completed were valid and the risk to the product on the market is very minimal. [REDACTED] agreed to provide this information [REDACTED]. [REDACTED] also agreed to review records for all devices that automatically record temperatures to data can be retrieved for the last three years and provide a report by [REDACTED].

Action

Notes For Next Inspection

5. Scroll to bottom of page and click on “Close Selected Action Items” (green arrow)
- Fill in Completion Comments (not required)
 - Fill in Completion Date (required) (red box)
 - Click on Close Selected Action Items (red arrow)

Complete Multiple Action Items

Completion Comments

Completion Date *

Close Selected Action Items

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II. CLOSING ACTION ITEMS WITH NOTES FOR NEXT INSPECTION

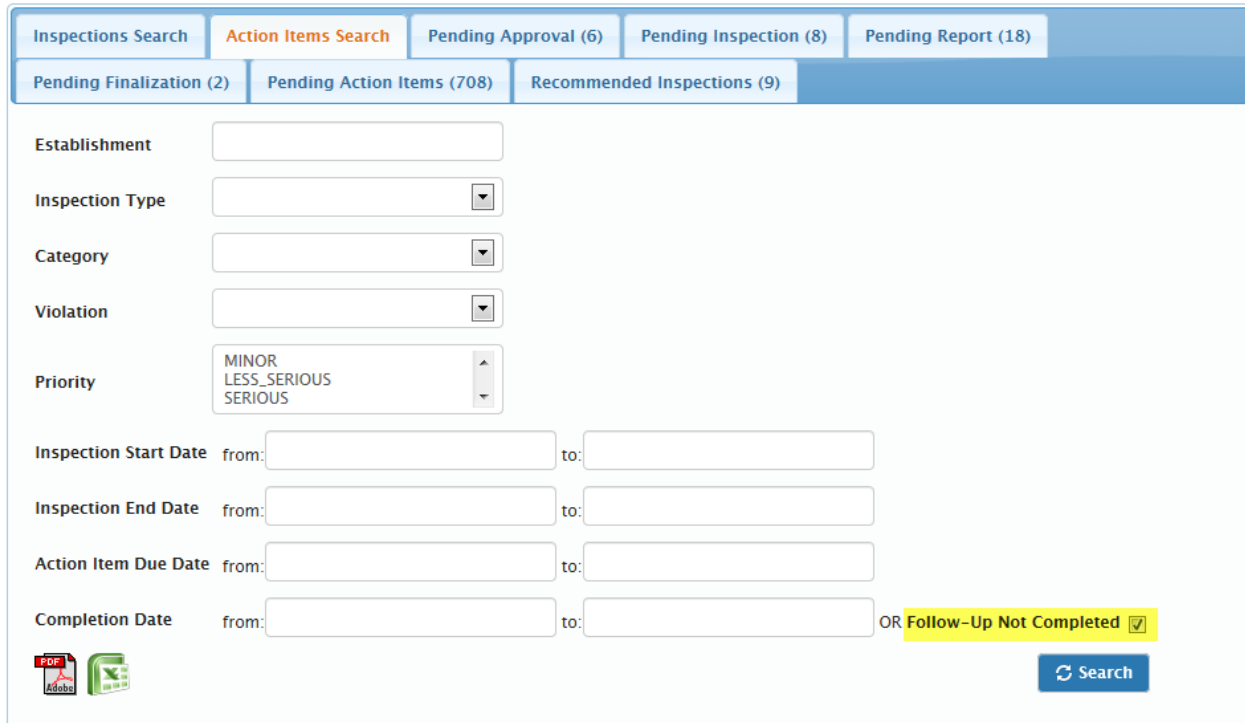
This method is used to close only one action item and a Note for Next Inspection is added, closed at the same time with the same response.

1. Go to Inspections Dashboard – Tab Action Items Search



The screenshot shows the top navigation bar of the LSRTIS system. The 'Action Items Search' tab is highlighted in orange. Other tabs include 'Inspections Search', 'Pending Approval (6)', 'Pending Inspection (8)', 'Pending Report (18)', and 'Pending Finalization (2)'. Below the main tabs, there are two sub-tabs: 'Pending Action Items (708)' and 'Recommended Inspections (9)'.

2. Use the search criteria to pull up the desired action items.



The screenshot shows the search interface for 'Action Items Search'. It includes several filter fields: 'Establishment' (text input), 'Inspection Type' (dropdown), 'Category' (dropdown), 'Violation' (dropdown), and 'Priority' (dropdown with options: MINOR, LESS_SERIOUS, SERIOUS). There are also date range filters for 'Inspection Start Date', 'Inspection End Date', 'Action Item Due Date', and 'Completion Date', each with 'from:' and 'to:' input boxes. A checkbox labeled 'Follow-Up Not Completed' is checked. At the bottom left, there are icons for PDF and Excel. A blue 'Search' button is located at the bottom right.

This search is more flexible and allows you to pin point exact action items, or use the click Follow-Up not completed to assist with the search.

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3. The results screen will look different that using the search under the Pending Action Items Tab. If you click on Inspection next to the inspection of interest, you will go to the same screen as noted in I.4 above. This will not allow you to enter Notes for Next Inspection. But if you click on Info (highlighted below), you will bring up a Show Action Screen

Inspection	Info	Est	Inspection Type	Location	Start Date	Category	Violation	Priority	Due Date
Inspection	Info		In-Depth			EQUIPMENT	113.26	SERIOUS	
Inspection	Info		In-Depth			FACILITIES	108.5(b)(1)	MINOR	
Inspection	Info		In-Depth			FACILITIES	108.8	MINOR	

Show Action Item

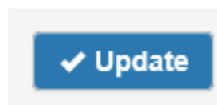
Inspection #	Establishment	Type	Leader	Members	Start Date	End Date	Last Inspection Date
10721		In-Depth					

Info

Category	FACILITIES
Priority	MINOR
Violation	108.5(b)(1)
Observation	The facility documents were reviewed and randomly compared to the physical facilities observed during the inspection. The following exception to the facility document was noted: Blueprint legend for Building [redacted] Room [redacted] did not describe the current function of the room. The room was designated as an office; however, we observed the storage of purchased media.
Action	[redacted] agreed to correct this discrepancy at the next revision of the blueprint legend
Action Item Due Date	[redacted]
Completion Date	
Notes For Next Inspection	

[Edit](#) [Delete](#)

4. Click on Edit
- Fill in Completion Date (required) [red box]
 - Fill in Completion Results (not required)
 - Fill in Notes for Next Inspection (not required but the reason you are using this method) (green box)



- d. Click on

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Action Item Category *

FACILITIES

Action Item Priority *

MINOR

Action Item Due Date *

()

Violation *

108.5(b)(1) - OR - [Q Search & Select](#)

Observation *

The facility documents were reviewed and randomly compared to the physical facilities observed during the inspection. The following exception to the facility document was noted: Blueprint legend for Building ■ Room ■ did

Action *

agreed to correct this discrepancy at the next revision of the blueprint legend

Completion Date *

Completion Results

Notes For Next Inspection

[✓ Update](#) [← Cancel](#)

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III. PRINT REPORT OF ACTION ITEMS

1. Go to Inspection Search Tab and fill out information
2. Click on Info
3. File - Print