

HOW-TO: COMPLETE AN INSPECTION

FOR: Inspectors, Mentors, and Trainees.

DESCRIPTION: Reviewing the applicant’s responses and documents prior to the inspection, documenting findings, and completing all the elements of inspection.

DEFINITIONS: NA

PREREQUISITES:

- [How-To: Log In](#), IT.GDE.8.003
- [How-To: Navigate the Portal-Inspector Guide](#), IT.GDE.8.026
- [How-To: Navigate the Application \(Inspector\)](#), IT.GDE.8.031
- [How-To: Navigate the Portal-Inspector Trainee Guide](#), IT.GDE.8.044

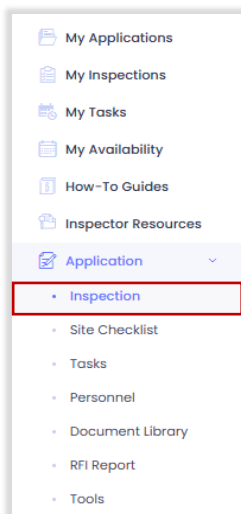
PROCESS:

1. Select **My Inspections** in the left navigation pane. Select **Inspection Overview**.



Helpful Hint: Review all information in the Portal prior to the day of inspection.

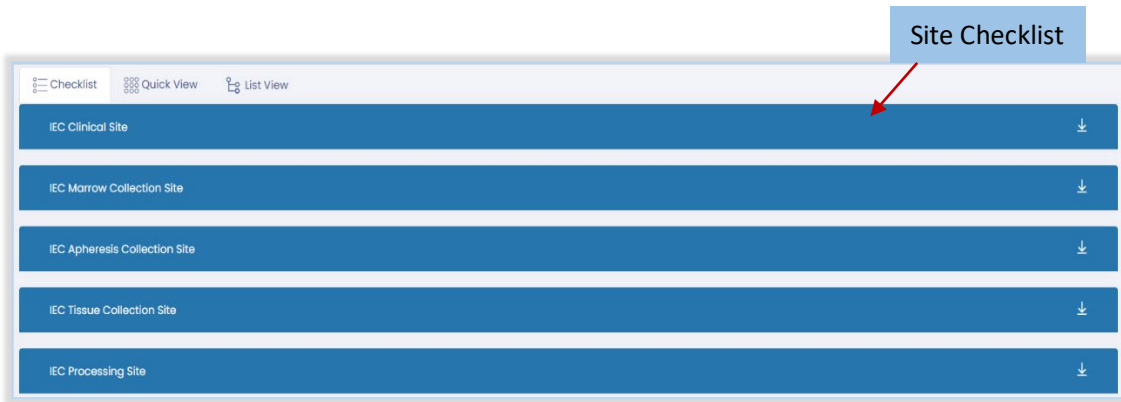
2. **Inspection Overview** is the overview of the inspectors’ tasks and statuses. Select **Inspection** in the left navigation pane or **Inspection Overview** in the navigation tabs.



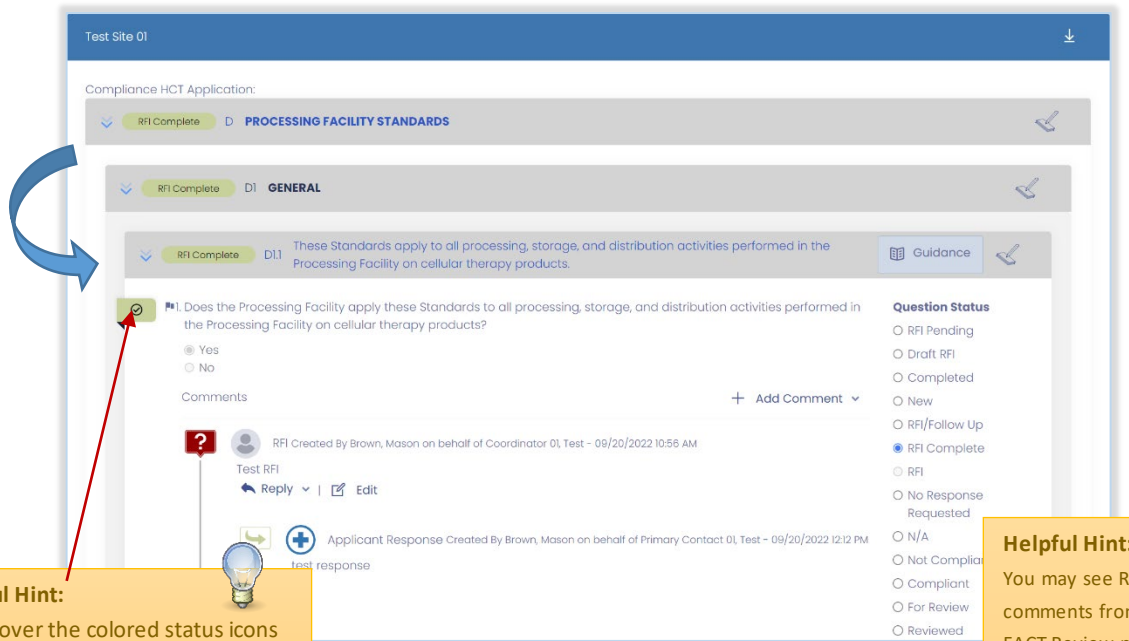
- a. Use the ribbon or tabs to navigate within the inspection.
- b. As inspection tasks are completed, the color of the arrows in the ribbon will change from yellow to green, a checkmark displays in the tab, and the red “No” will change to a green “Yes” in the table.
- c. To review progress, return to the **Inspection Overview** tab.

Name	Role	Inspection Category	Site Inspection Date	Site	Site Checklist Complete	Organization Description Complete	Overall Impressions Complete	Clinical Outcomes Complete	Data Audit Complete	Inspection Interviews Complete	Trainee Feedback	Trainee Evaluation	Mentor Evaluation	Inspection Process Evaluation	Inspection Finalized
Test Inspector 1	Lead Inspector	Adult/Pediatric Clinical	03/02/2025	Test Organization Clinical Site	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes	Yes
Test Inspector 1	Inspector	Narrow Collection	03/02/2025	Test Organization Morrow Site	Yes	Yes	Yes	N/A	Yes	Yes	N/A	N/A	N/A	Yes	Yes
Test Inspector 2	Inspector	Apheresis Collection	03/02/2025	Test Organization Apheresis Site	Yes	Yes	Yes	N/A	Yes	Yes	N/A	N/A	N/A	Yes	Yes
Test Inspector 3	Inspector Mentor	Minimal/None From Minimal Processing	03/02/2025	Test Organization Processing Site	Yes	Yes	Yes	N/A	Yes	Yes	Yes	N/A	Yes	Yes	Yes
Trainee Inspector	Inspector Trainee	Minimal/None From Minimal Processing	03/02/2025	Test Organization Processing Site	Yes	Yes	Yes	N/A	Yes	Yes	N/A	Yes	N/A	Yes	Yes

3. Select *Complete Site Checklist* in the ribbon to view each checklist assigned to a site.



4. For each site, expand the checklist to the lowest level until all questions display.

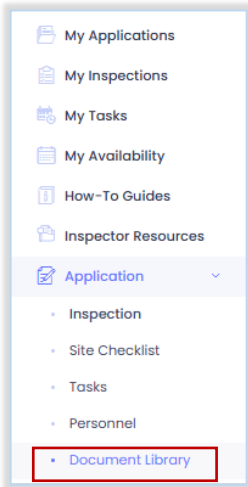
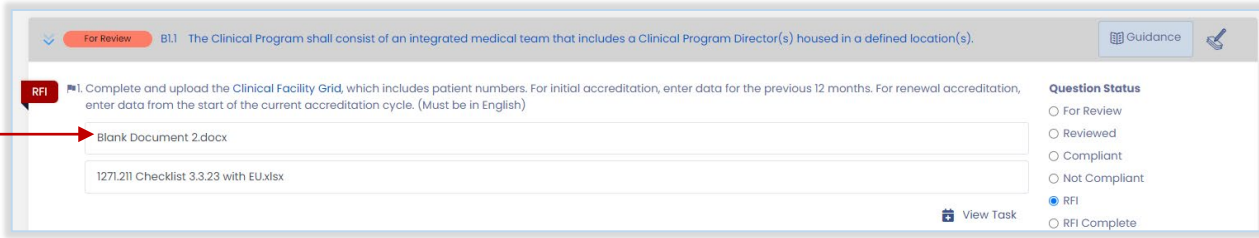


Helpful Hint:
Hover over the colored status icons to view the status description.

Helpful Hint:
You may see RFI comments from the FACT Review phase. Reviewing this information will help you in your assessment.

5. View Submitted Documents

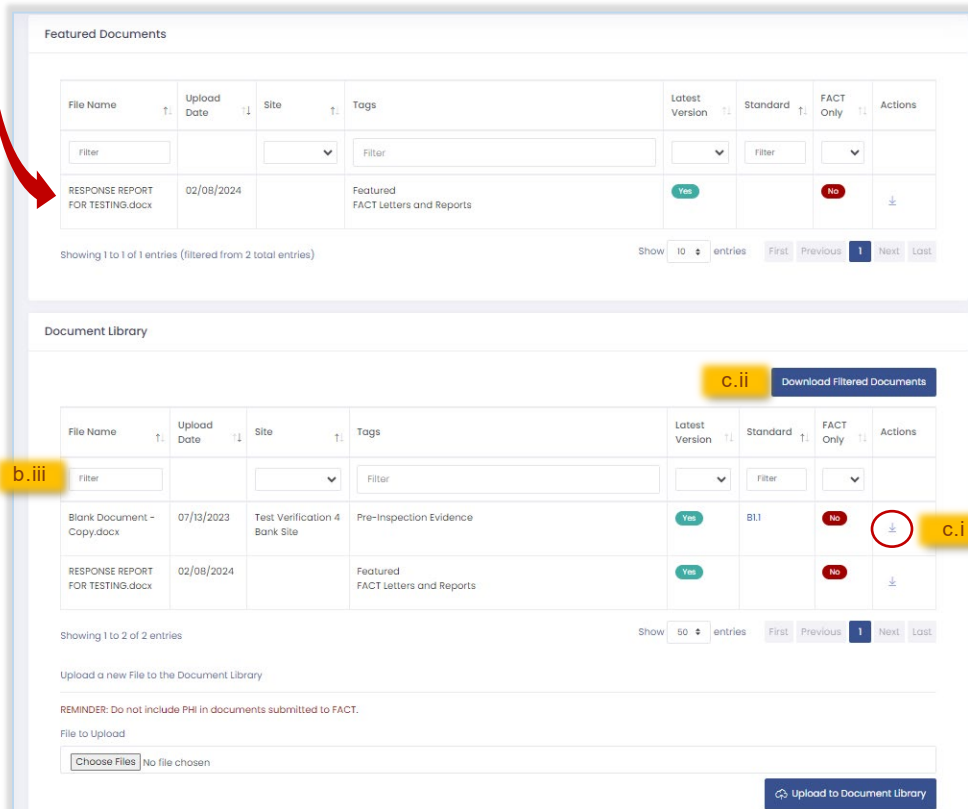
- a. To view a document within the site checklist, select the link (document name) in the question to download the document while reviewing the site checklist.



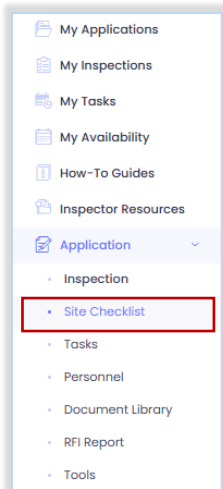
- b. To view documents within the **Document Library**:







- i. Select **Document Library** in the left navigation pane. The Document Library is organized by columns: *File Name*, *Upload Date*, *Site*, *Tags*, *Latest Version*, *Standard(s)*, *FACT Only*, and *Actions*.
- ii. The tools in each column can be used to filter and sort to locate documents.
- iii. If performing a renewal inspection, locate the **Response Report** from the previous FACT inspection in the document library and verify continued compliance on-site.

The report should be tagged and located in the Featured Document area or can be found by searching for "response" in the File Name field of the document library.



- c. Download documents in the **Document Library**:
 - i. To download a document, select the icon in the *Actions* column.
 - ii. To download multiple documents, use the filter and sort tools. Select the **Download Filtered Documents** button to download all filtered documents into a zip folder.
- 6. Within the **Site Checklist**, review the applicant’s response and indicate compliance for each question, if applicable. If clarification or additional documentation is needed, enter an RFI. Submit RFIs to FACT at least two (2) weeks prior the inspection.
- 7. Prior to the inspection, enter only *RFIs*, *FACT Only*, *Commendable Practice*, or *Inspector Note* comments. Post inspection, enter a comment for an *RFI*, *Citation*, *Suggestion*, *Commendable Practice*, or *Inspector Note* in the field provided.
 - a. Select **+ Add Comment**.
 - b. Select the comment type.



Comment Type		Description
RFI*		Request for Information; clarification or additional documentation is required. Used pre-inspection.
Citation**		Standard is not met, used post-inspection.
Suggestion**		Standard is met; however, practice could be improved. Used post-inspection.
FACT Only		Comment for FACT, does not display on report. Used pre- or post-inspection.
Commendable Practice		A practice is identified that is commendable, does not display on report. Can be used pre-or post-inspection.
Inspector Note		Comment for Inspector, does not display on report. Used pre-inspection to assist in the process, e.g., document questions to ask during the inspection. This is available when exporting the checklist, the inspector note field may be included.

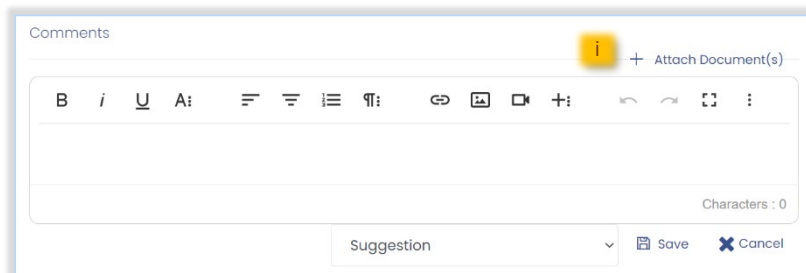
* **Pre Inspection Action**: after entering an RFI, you must notify the lead inspector to submit

** **Post Inspection Action**: enter only during the inspection or post-inspection.

the RFI. The lead inspector is responsible for submitting all team members’ RFIs to FACT.

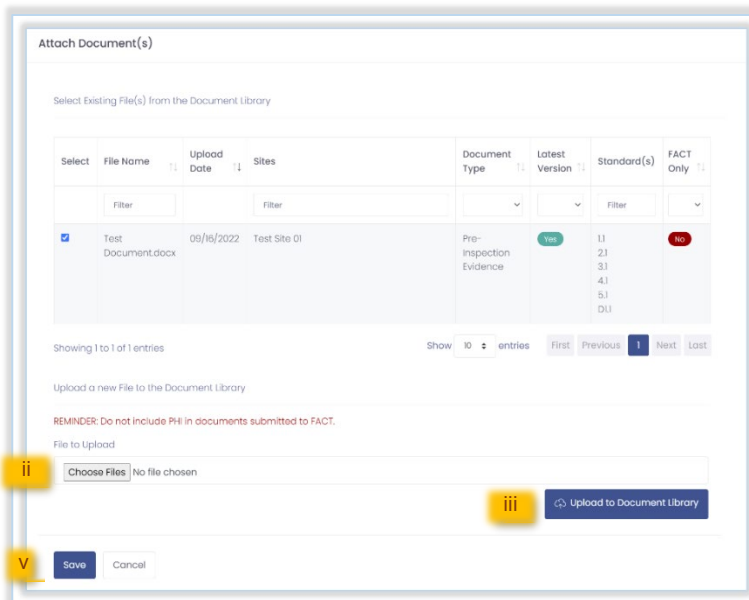
- c. If needed, append supporting documentation by attaching the document to a comment
Note: this function is more commonly used by the applicant.

- i. Select **+Attach Document**. The Document Library window displays.
- ii. Select **Choose Files** to locate the file for upload.

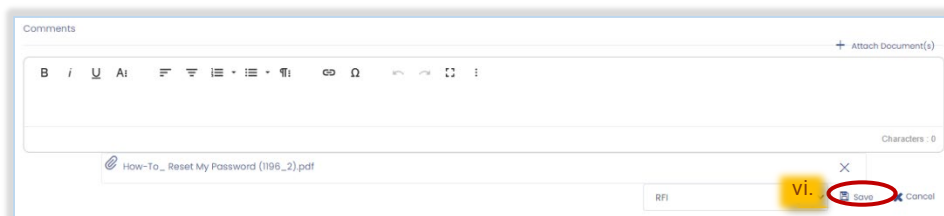


- Update the file name as needed to reflect the document’s content.

- iii. Select **Upload to Document Library**.
- iv. The newly uploaded document will be automatically selected.
- v. Select **Save** in the **Attached Document(s)** window to finish selecting the documents and close the window.



- vi. Select **Save** in the **Comments** window to save the comment associated with the attached document. Continue review of all requirements.

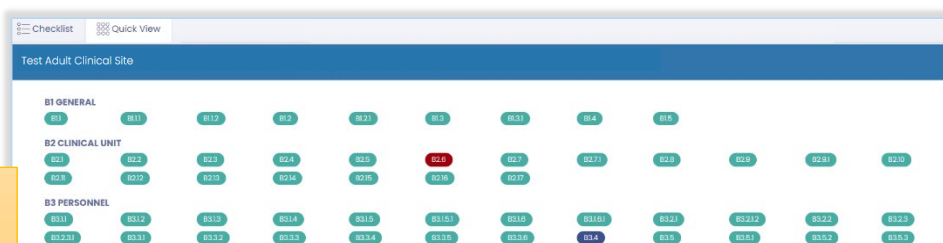


Post Inspection Action: Continue your review of each requirement until all requirements are either *Compliant*, *Not Compliant*, or *Not Applicable*.

- 8. If a question is marked as RFI:
 - a. The **Send RFIs to FACT** button will display for the **Lead Inspector**.
 - b. If Inspection Team members enter RFIs they must notify the **Lead Inspector** via email.



- c. The **Lead Inspector** submits the RFIs to FACT.
- d. After FACT sends the RFIs, Inspectors may continue to review the application. The application status changes to *RFI In Progress*. For questions with an RFI status of *In Progress*, it is

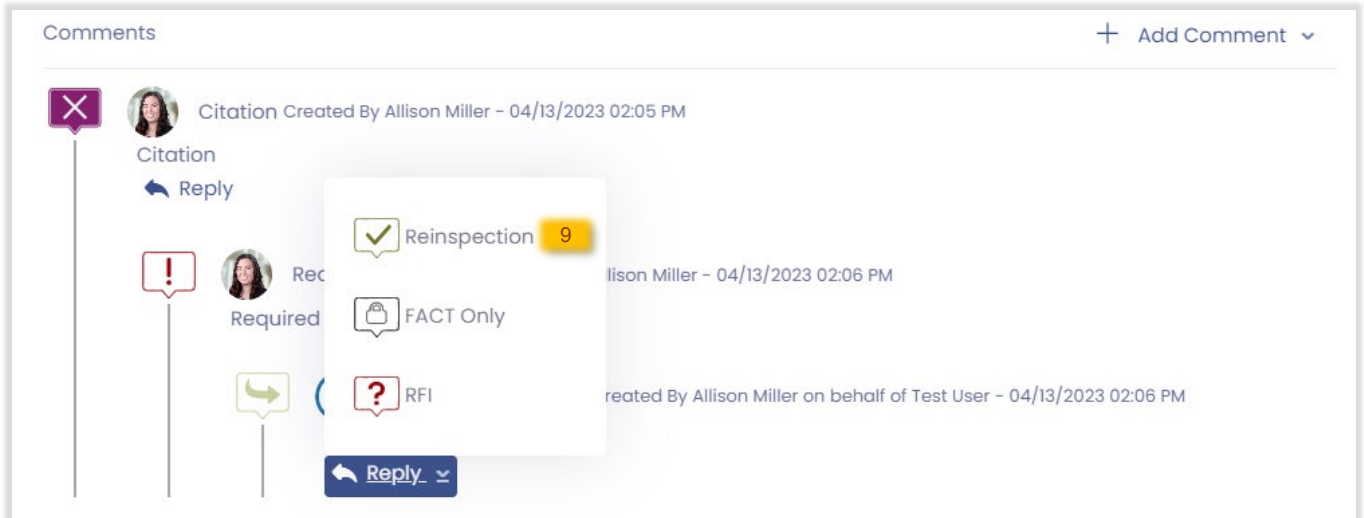


Helpful Hint:
 Hover over the standard to view the status.

Inspector Quick View with RFI

recommended to work on other questions until the organization has submitted their response to the RFIs.

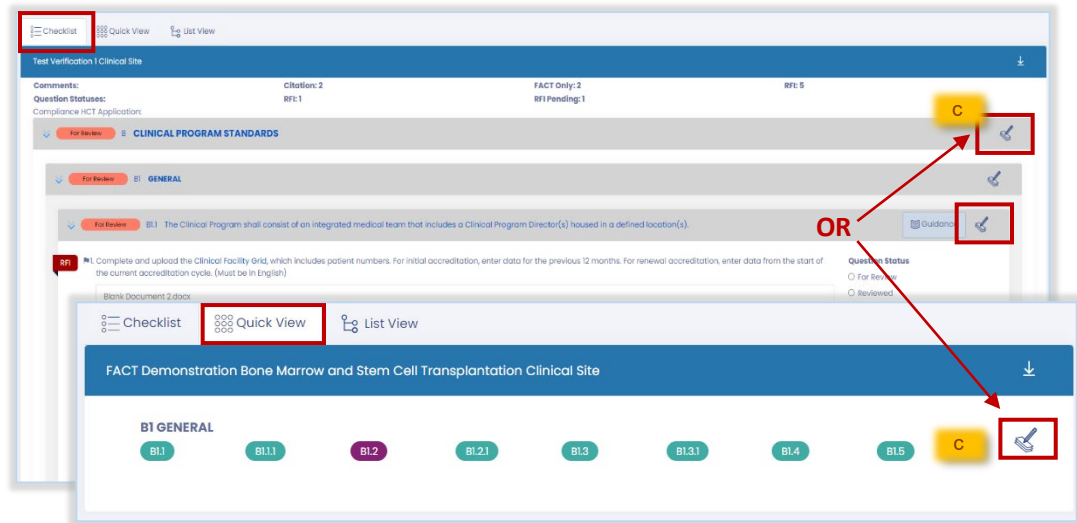
9. Reinspection Comments, if performing a reinspection:
 - a. Prior to the reinspection, there is an option available to include reinspection comments alongside the applicant’s response comment.



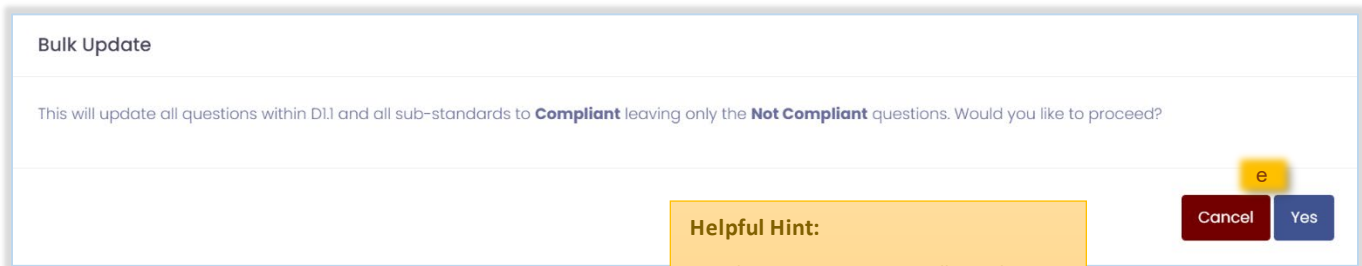
Post Inspection Action: After the inspection, for each deficiency, ensure a detailed description of the citation is entered. The question status updates to *Not Compliant*. Mark questions without deficiencies as *Compliant*. For instructions on performing a bulk update, refer to the steps below.

10. Bulk Status Update: **Post Inspection Action** only.
 - a. After marking each applicable question as *Not Compliant* and entering the deficiency comments, inspectors may perform a **Bulk Status Update** to mark the remaining standards as *Compliant*. This can be performed in *Checklist* view or *Quick View*.

- b. For each site, expand the checklist down to the level intended for inclusion in the bulk update.



- c. Select the **Bulk Update** icon within the *Checklist* or *Quick View*.
- d. A warning notice displays.
- e. Select **Yes** to complete the bulk update or **Cancel** to stop the action and return to the application.



Helpful Hint:
As a best practice, manually update the specific questions you want to mark as *Not Compliant*, then use bulk update to mark the remaining questions *Compliant*.

Organization Description

11. Each inspector must review and verify the accuracy of the *Organization Description*.
12. If this is a renewal inspection, content from the previous inspection will prepopulate in the field.
13. **Non-lead inspectors:**
 - a. May enter suggestions for changes in the *Discussion* comments at the bottom of the page.
 - b. When done, select **Save Comment**. Then select **Mark Complete**.
 - c. If the information is accurate and no changes are needed, select **No Changes Requested**. The section updates to *Complete*.
14. **Lead Inspectors:**
 - a. May make edits to the *Organization Description* field as needed.

- b. Lead Inspectors should review the comments from the inspection team members at the bottom of the page.

Organization Description

Description of Organization
Please review for accuracy and update as needed. The following description must include:

- Name and physical location of each facility/site
- Description of services and procedures performed
- Physical layout of each facility/site including critical equipment
- Personnel
- Spatial relationship among facilities/sites

Add Comment

13.a Characters : 0

14.b

13.b Characters : 0

Save Comment

Discussion Add comments to notify the lead of any changes needed for the Site Description or Spatial Relationship fields.

13.c Characters : 0

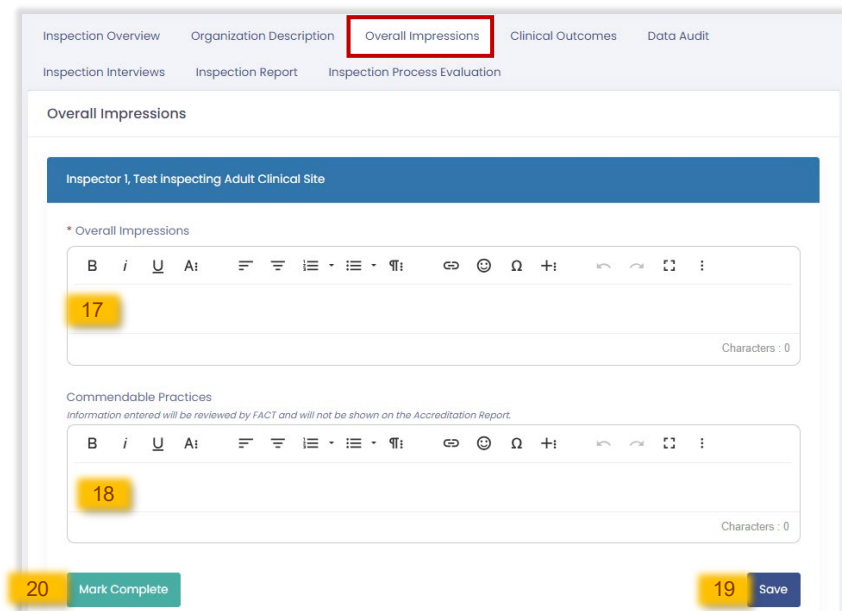
Mark Complete No Changes Requested Save

- c. If changes are made, select **Mark Complete**.
- d. A **Summary of Changes** window displays. Enter a summary of the changes.
- e. Select **Submit**. The FACT coordinator uses this information to identify the changes.
- f. If there are no comments or changes to submit, select **No Changes Requested**. The system will compare the fields with the original values and warn that changes will be lost, if applicable
15. Once this section is complete, a green checkmark will display in front of the tab and the ribbon arrow color will change from yellow to green.

Overall Impressions

Post Inspection Actions

16. Each inspector must review and enter *Overall Impressions*. The *Commendable Practices* field is optional.
17. Enter the **Overall Impressions** of the site.



The screenshot shows the 'Overall Impressions' section of the FACT Accreditation Portal. The 'Overall Impressions' tab is highlighted with a red box. Below the navigation tabs, the form title is 'Inspector 1, Test Inspecting Adult Clinical Site'. There are two main text input areas: one for 'Overall Impressions' (labeled 17) and one for 'Commendable Practices' (labeled 18). Both areas have a rich text editor toolbar and a 'Characters: 0' indicator. At the bottom of the form, there are two buttons: 'Mark Complete' (labeled 20) and 'Save' (labeled 19).

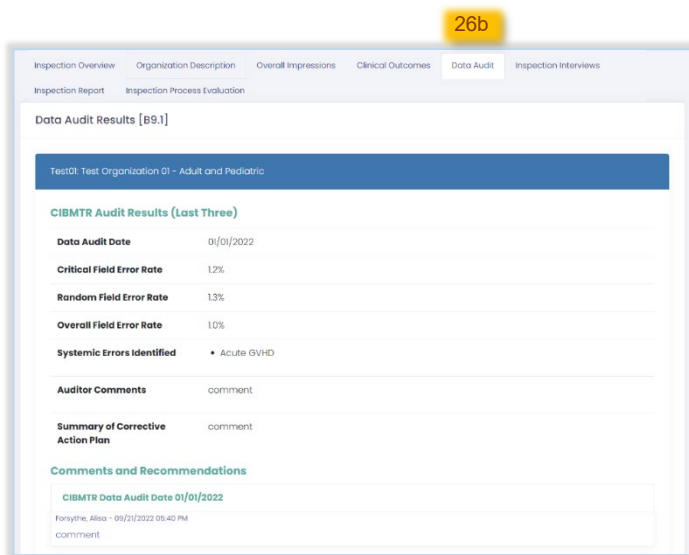
18. If there are **Commendable Practices**, not related to clinical outcomes or data management, enter them in the field.
19. If edits have been made and there is a need to return later, select **Save**.
20. After the required fields have been entered, select **Mark Complete**.
*Note: After marking complete, the fields can be edited until the **Finalize Report** button is selected in the **Inspection Report** tab.*
21. Once this section is complete, a green checkmark will display in front of the tab and the ribbon arrow color will change from yellow to green.

Clinical Outcomes and Data Management

22. All inspectors (except for the clinical inspector responsible for completing the *Data Audit* section) are required to be aware of the program's data accuracy status and must acknowledge the results in the *Data Audit* section. Select the CIBMTR number to expand the section to review the data, then select **Acknowledge**.
23. **Clinical Inspectors** are responsible for completing the *Clinical Outcomes* and *Data Audit* sections of the application.
24. For each CIBMTR number, there are Clinical Outcomes and Data Audit information to review.
25. Select each CIBMTR number to expand.
26. **Before the inspection:** review the information provided by the Clinical Outcomes Improvement Committee and the FACT-CIBMTR Data Audit Committee in the *Clinical Outcomes* (26a) and *Data Audit* (26b) sections. This includes specific requests for information to review with the program during the inspection.
27. **Post Inspection Action:** enter responses in the required fields for both *Clinical Outcomes* and *Data Audit* sections.
 - a. Select **Mark Complete** if finished.
 - OR
 - b. **Save** to record entry and return later.

*Note: After marking complete, the fields can be edited (select **Save** to save changes) until the **Finalize Report** button is selected in the *Inspection Report* tab.*

28. Once these sections are complete, a green checkmark will display in front of the tabs and the ribbon arrow color will change from yellow to green.



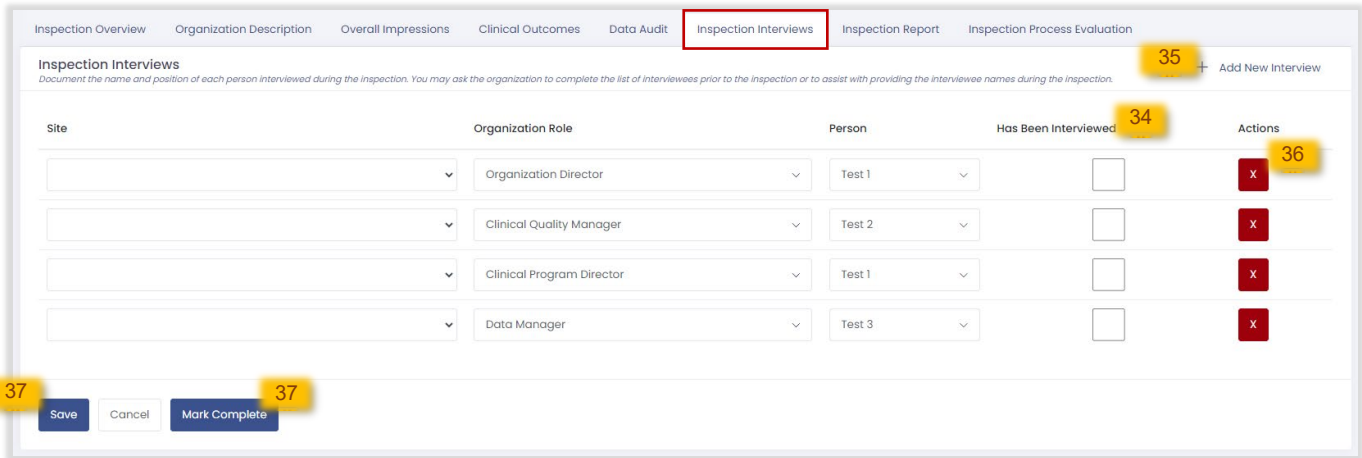
Inspection Interviews

29. The **Inspection Interviews** tab tracks the interviews performed during the inspection.
30. In the **Organization Role** column, specific values prepopulate with the roles that must be interviewed during the inspection. If a role is not listed, it may be entered manually.
31. Review the list of personnel to be interviewed prior to the inspection.

Post Inspection Actions:

32. In the **Site** column, select the site where the interview occurred for each individual.
33. In the **Person** column, select the name of the staff member interviewed. If the name is not listed, enter the person's name.
34. In the **Has Been Interviewed** column, check the box to indicate that the interview was completed.
35. To add a new interview, select the **+ Add New Interview** button at the top.
36. To remove an interview, in the **Actions** column select the red X.
Note: this feature may be used in cases where an individual was inadvertently mentioned more than once or if removal of excess rows is required.
37. Select **Mark Complete** if finished OR **Save** to record entry and return later.
*Note: After marking complete, the fields can be edited (select **Save** to save changes) until the **Finalize Report** button is selected in the **Inspection Report** tab.*

38. Once this section is complete, a green checkmark will display in front of the tab and the ribbon arrow color will change from yellow to green.



Inspection Interviews
 Document the name and position of each person interviewed during the inspection. You may ask the organization to complete the list of interviewees prior to the inspection or to assist with providing the interviewee names during the inspection.

Site	Organization Role	Person	Has Been Interviewed	Actions
<input type="text"/>	Organization Director	Test 1	<input type="checkbox"/>	<input type="button" value="X"/>
<input type="text"/>	Clinical Quality Manager	Test 2	<input type="checkbox"/>	<input type="button" value="X"/>
<input type="text"/>	Clinical Program Director	Test 1	<input type="checkbox"/>	<input type="button" value="X"/>
<input type="text"/>	Data Manager	Test 3	<input type="checkbox"/>	<input type="button" value="X"/>

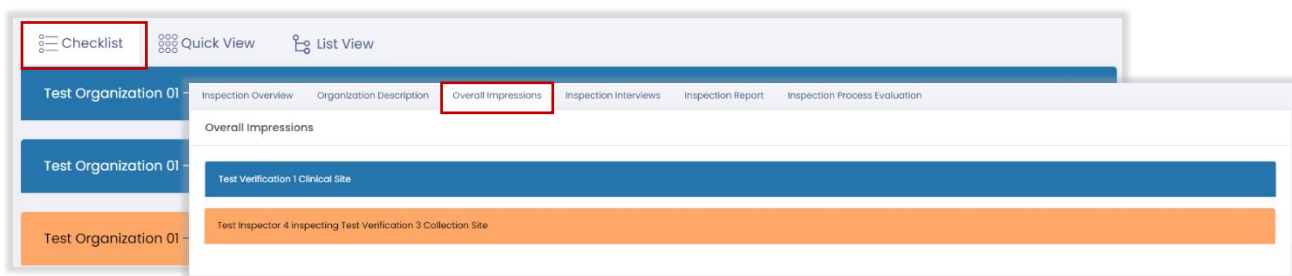
Mentor Tasks

Post Inspection Actions:

39. Inspectors with a Mentor role have an area to document Mentor feedback. This area is named:
- Trainee Inspection Reports* in the navigation tabs.
 - Mentor Feedback* in the ribbon.

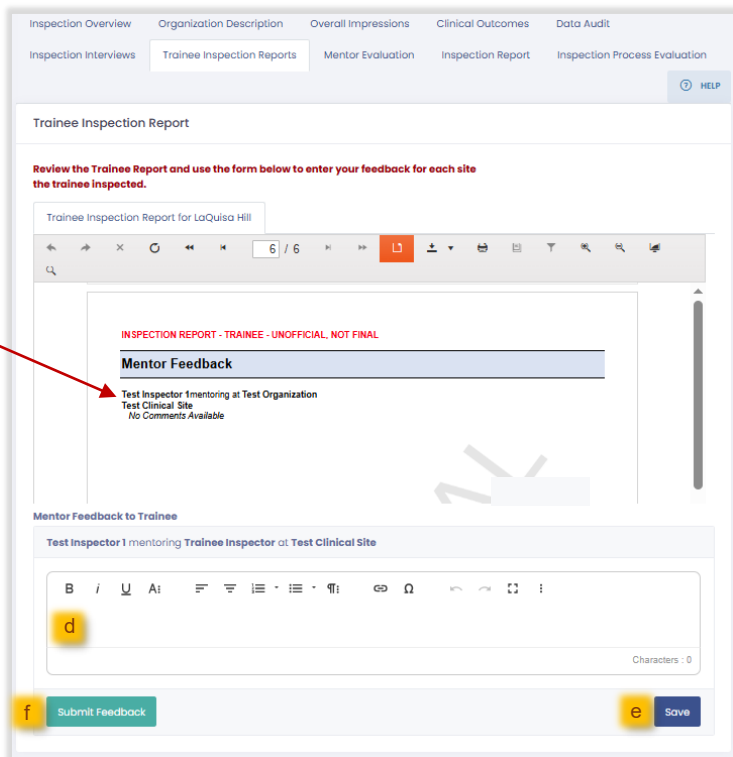


40. The Trainee's Site Checklist and Overall Impressions display orange.



41. Review the *Trainee Inspection Report* and enter feedback for the Trainee.

- Select **Trainee Inspection Reports** OR **Mentor Feedback**.
- The *Mentor Feedback* window displays.
- Review the trainee inspection report.
- Complete the *Mentor Feedback* field below the Trainee Inspection Report.
- Select **Save** to record your entry. This option allows you to return to make edits if needed.
- Select **Submit Feedback** to finalize your response. This renders the area as read-only.
- The Mentor's feedback comments display at the bottom of the *Trainee Inspection Report*.



h. Once complete, a green checkmark will display in front of the tab and the ribbon arrow color will change from yellow to green.

42. Complete the mentor evaluation in the portal.

Note:

- If **Mark Complete** is inadvertently selected prior to completing the evaluation, the evaluation can be accessed here: <https://www.surveymonkey.com/r/9YMP8RV>.

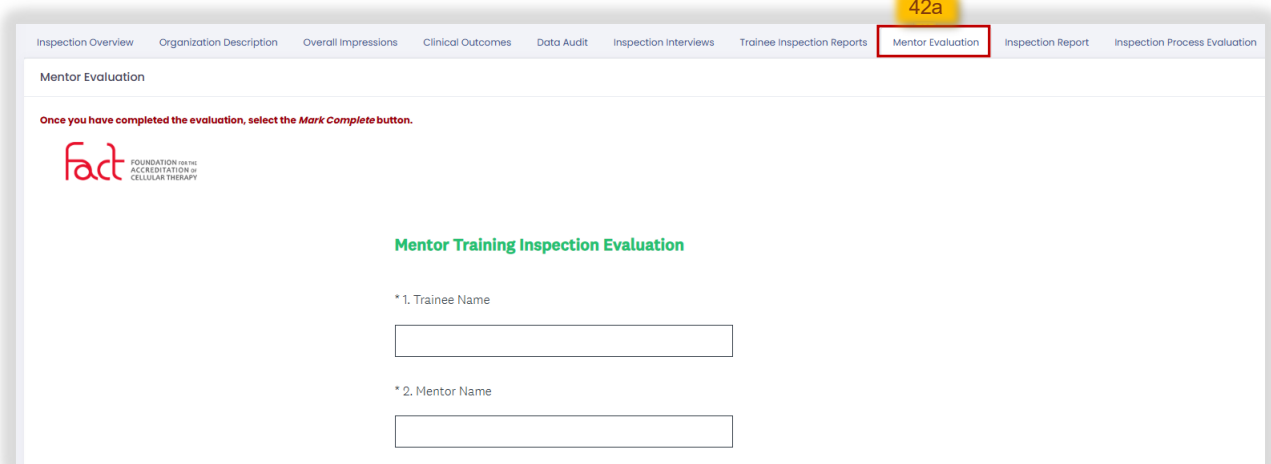
- Complete the evaluation when the trainee inspection report is finished. Do not navigate to other windows until the evaluation is complete as responses will not be saved.

a. Select **Mentor Evaluation**. The Mentor Evaluation window displays and includes the Mentor Training Inspection Evaluation.

b. Complete the Evaluation.

c. Select **Submit** then **Mark Complete**.

d. Once complete, a green checkmark will display in front of the tab and the ribbon arrow color will change from yellow to green.



42a

Inspection Overview Organization Description Overall Impressions Clinical Outcomes Data Audit Inspection Interviews Trainee Inspection Reports **Mentor Evaluation** Inspection Report Inspection Process Evaluation

Mentor Evaluation

Once you have completed the evaluation, select the **Mark Complete** button.

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Mentor Training Inspection Evaluation

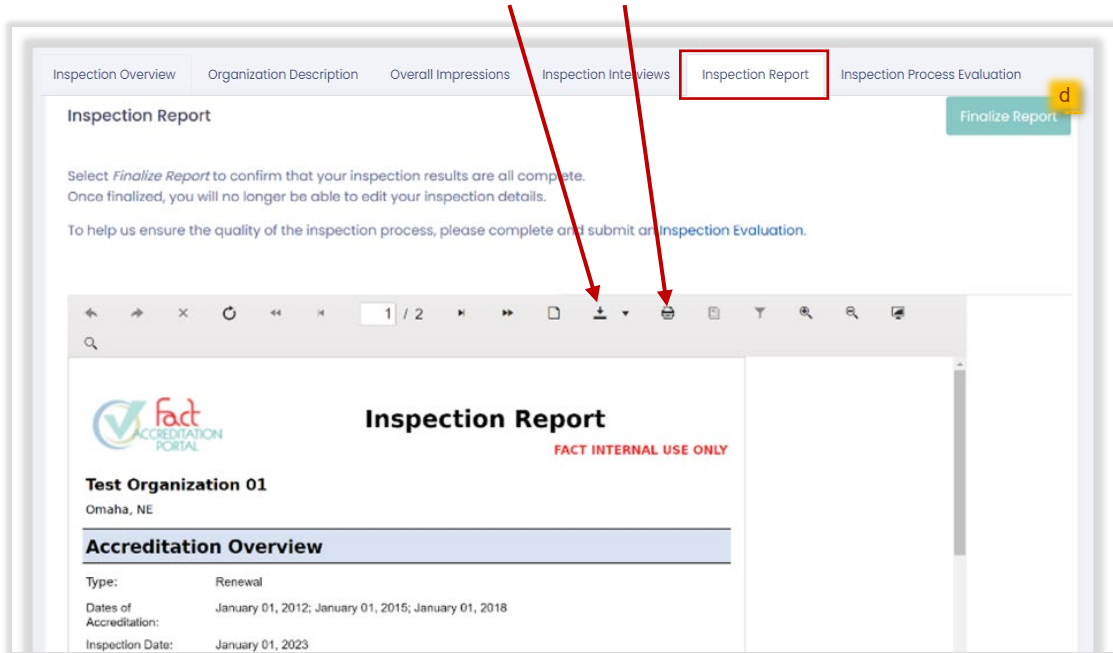
* 1. Trainee Name

* 2. Mentor Name

Finalizing the Inspection and Report

Post Inspection Actions:

43. After the inspection is complete, before finalizing the inspection report, review all the tabs and ensure all required data is present, including completion of the inspection process evaluation, refer to step 45.
44. Finalize the Inspection Report
 - a. Select the **Inspection Report** tab.
 - b. Use the report action menu to download or print the report.



- c. Review the *Inspection Report* for accuracy and completeness.
- d. Select **Finalize Report**.
- e. Once all inspectors have finalized the *Inspection Report*, the **Submit to FACT** button displays to the **Lead Inspector**.
- f. The **Lead Inspector** reviews the *Inspection Report* in its entirety. After determining the report is complete and accurate, select **Submit to FACT** to submit the completed report.



- g. The application status changes to *Post Inspection Review* and FACT is notified.

Helpful Hint:

Once the Inspection Report is Finalized, everything will be read only.

Inspection Process Evaluation

45. Select the *Inspection Process Evaluation* tab.

46. Complete the evaluation.

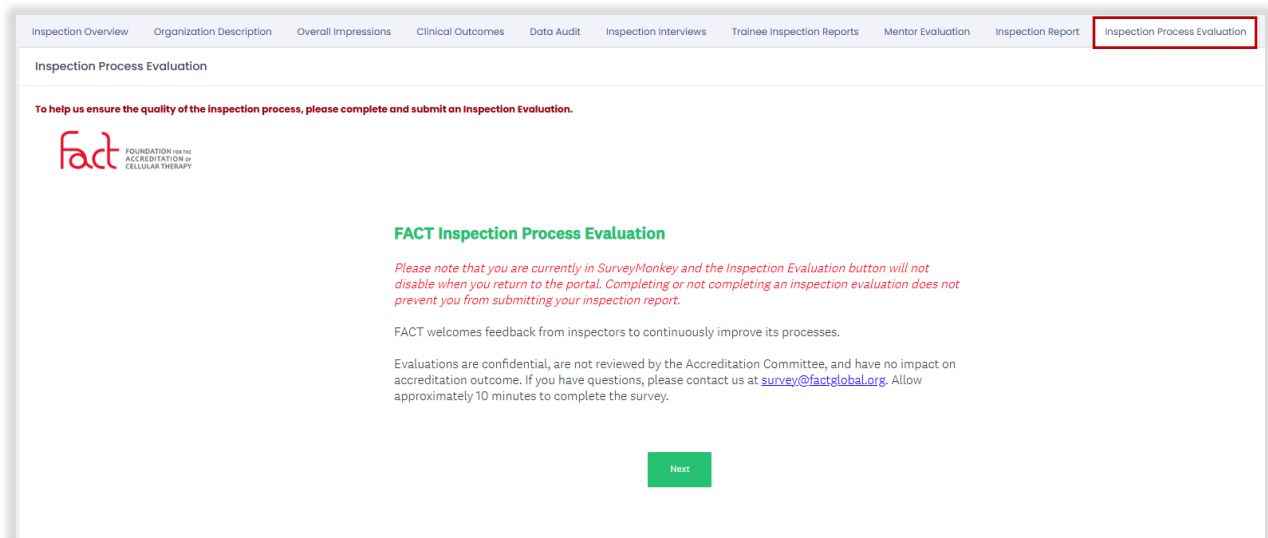
Note: Complete the evaluation when the inspection report is finished. Do not navigate to other windows until the evaluation is complete as responses will not be saved.

47. Select **Submit** then **Mark Complete**.

48. Once complete, a green checkmark will display in front of the tab and the ribbon arrow color will change from yellow to green.

Note: It is requested that all inspectors complete an *Inspection Evaluation* before selecting **Finalize Report** (the link may be used to access the *Inspection Evaluation* any time after finalizing:

<https://www.surveymonkey.com/r/P7BHH97>).

A screenshot of the FACT Accreditation Portal's 'Inspection Process Evaluation' survey page. The page has a navigation bar at the top with tabs for 'Inspection Overview', 'Organization Description', 'Overall Impressions', 'Clinical Outcomes', 'Data Audit', 'Inspection Interviews', 'Trainee Inspection Reports', 'Mentor Evaluation', 'Inspection Report', and 'Inspection Process Evaluation'. The 'Inspection Process Evaluation' tab is highlighted with a red border. Below the navigation bar, the page title is 'Inspection Process Evaluation'. A red banner reads: 'To help us ensure the quality of the inspection process, please complete and submit an Inspection Evaluation.' The FACT logo is displayed on the left. The main content area features the title 'FACT Inspection Process Evaluation' in green, followed by a red note: 'Please note that you are currently in SurveyMonkey and the Inspection Evaluation button will not disable when you return to the portal. Completing or not completing an inspection evaluation does not prevent you from submitting your inspection report.' Below this, it states: 'FACT welcomes feedback from inspectors to continuously improve its processes.' and 'Evaluations are confidential, are not reviewed by the Accreditation Committee, and have no impact on accreditation outcome. If you have questions, please contact us at survey@factglobal.org. Allow approximately 10 minutes to complete the survey.' A green 'Next' button is centered at the bottom of the page.