ZOT hSCRO

Staff Guide

October 2023

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Overview of Huron Safety

The Huron Safety system provides a mechanism for tracking and managing safety issues for research projects, including inspections and safety incidents.

Huron Safety supports the following submission types.

Submission Types in Huron Safety	
Type	**Description**
Initial Submissions	
Protocol	Documents the aspects of a research project that pose a potential safety risk to humans or animals and the precautions that will be taken to mitigate those risks. In this guide, “protocol” also refers to the representation of a safety protocol in the Safety solution. The protocol submission consists of a number of forms and attachments that contain the research and experiment details.
Follow-on submissions	
Amendment	Changes to an approved protocol. The amendment submission consists of a form that lists amendment details along with the updated protocol pages.
Continuing Review	A review of an approved protocol. Protocols involving radiation must go through an annual review. Other types, such as biosafety, are typically initiated on need basis. However, your institution may require all protocols to go through an annual review. The continuing review submission consists of a form on which you record any changes, accidents or other problems that have occurred since the protocol was approved, or since the previous continuing review.
Amendment/CR	Request changes to an approved protocol and extension of the approval period in a single submission. The Amendment/CR submission consist of both amendment and containing review forms.
De Novo Review	A De Novo submission is a three-year approval period after which the protocol starts over again. The submission is a copy of the existing protocol with the same PI and title but a new ID and a last day of de novo review period date.
Other Follow-on Submission	
Incident	Documents any condition or event that could cause harm or that violates safety regulations. Any registered user can initiate an Incident.
Inspection	Documents an inspection of a facility, such as an annual radiation inspection or an ad-hoc biosafety inspection. Allows creation of findings that require corrective action, and which appear as acknowledgment on a safety committee meeting agenda.

The activities a user can perform in Huron Safety are determined by the roles assigned to that user. Some of the Safety roles defined in the following table are fundamental, predefined user roles, but others are secondary roles that must be explicitly assigned in Huron Safety. For example, “Study Staff” is a fundamental user role, whereas “PI” is a contextual role; a user with the Study Staff role must be explicitly assigned the role of “PI.” For additional information on roles, see the Safety Deployment Guide.

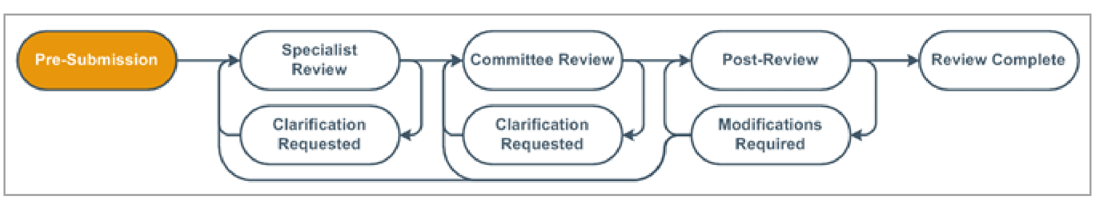
Roles in Huron Safety	
Position	**Typical Activities**
PI	The Principal Investigator (PI) listed on the submission. While others assist the PI in developing and editing the submission, only the PI (or designated PI proxies) can submit the protocol or follow-on submission to start the review process.
Registered User	Users authorized to create an incident.
Protocol Team	Individuals involved in developing the submission and listed on the submission as protocol team members. The protocol team always includes a PI but can also include a PI proxy, other co-investigators, science contributors, and administrative staff.
Safety Specialist	Individuals who guide submissions through the review process. The specialist reviews a newly submitted protocol for completeness, determines the level of review it needs, and ensures correspondence with the PI is completed in a timely manner.
Safety officer	This is a generic term used for any individual who is responsible for reviewing safety protocols and follow-on submissions. The Safety officer roles that can be assigned are Biosafety Officer, Radiation Safety Officer and, Chemical Safety Officer.
Committee Member	Individuals on a Safety committee.
Committee Chair	A Safety committee member assigned to chair the committee.
Safety Administrator	An individual with Safety oversight responsibilities. Can perform the same actions as specialists, but is typically less involved in the day-to-day processing of submissions.
Committee Administrator	An individual responsible for managing committee meetings.
Site Manager	An individual who has system-wide access. This includes full access to security and system settings, and all data, work-spaces, activities, and actions in the system.

Overview of Safety Submission Workflow

The Huron Safety solution enables protocol teams to submit safety protocols and follow-on submissions (amendments and continuing reviews) for review by the Safety committee and other personnel with Safety-related roles. The Huron Safety system shepherds protocols through a series of states based on the actions of personnel participating in the review cycle.

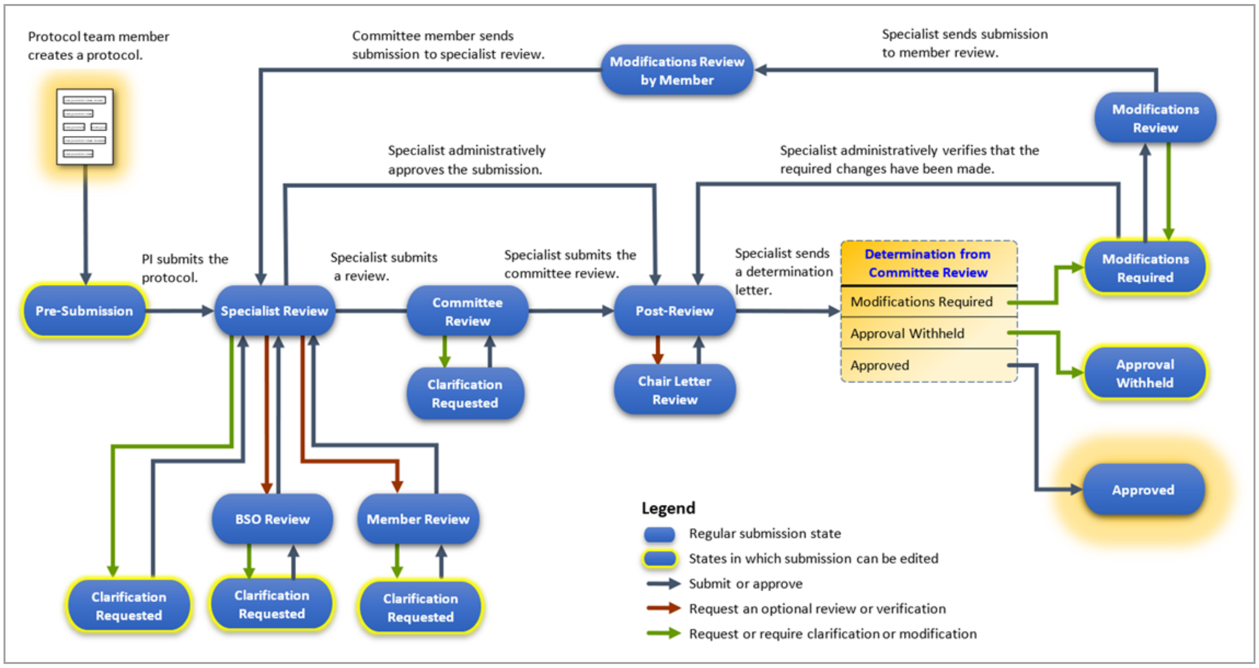
- A member of the protocol team enters a new protocol into the system, which puts it into the Pre-Submission state. When the PI submits it for review, its state changes to Specialist Review.
- During Specialist Review, the Safety specialist assigned to oversee this process reviews the protocol and determines which additional reviews (if any) are needed—biosafety officer review (for biosafety protocols only), member review, and/or committee review. If the protocol goes through a biosafety review or member review, the protocol returns to the assigned specialist when that review is complete so the specialist can determine the next course of action. When a protocol is in the Specialist Review state, the specialist can decide to administratively approve the protocol thereby bypassing committee review and moving it directly to the Post-Review state.
  Note: Depending on your institution's settings, a Safety specialist can also be able to edit the submission in any state up to the Approved state.
- At any point during a specialist, biosafety, or member review, a reviewer can request changes to the protocol resulting in a back and forth exchange between the PI and reviewer before the reviewer submits a review.
  Note: Assigned members can execute the Request Clarification by Member activity if the corresponding Safety setting is enabled.
- After all the requested biosafety and member reviews are complete, if the specialist determines a committee review is needed, the specialist submits a review and the protocol moves to the Committee Review state. The appropriate Safety committee reviews the protocol during a committee meeting. The committee can also request clarification from the protocol team as needed to come to a determination.
- Generally, the specialist enters the committee determination in the system, which moves the protocol to the Post-Review state. During Post-Review, the specialist prepares the decision letter and sends it to the protocol team.
- If the protocol is approved, the submission moves to the Approved state. If not approved, depending on the determination, the protocol might cycle back through some part of the review process again.
- Once the protocol is approved, the protocol team can submit Amendments, Continuing Reviews or a single submission that includes both Amendment and Continuing as required by the institution. The single submission of Amendment/CR can only be submitted if there is no existing open CRs and / or an existing amendment of the same type. Amendments and Continuing Reviews follow the same review process as the original protocol submission.
- Depending on your institution's settings, you can also submit de novo reviews considering that there are no active follow-on submissions. A de novo review is a three-year approval period after which the protocol is started over again. Once the de novo submission is approved, the parent protocol moves to closed and the de novo submission becomes an active protocol.

The Huron Safety workspace displays the high-level view of the review process shown below, highlighting the stage of the process the protocol is currently in.



Workflow States and Transitions

This diagram shows some of the more common states and transitions a Safety protocol might go through during the review process. A submission workflow actually depends on the actions, choices, and data entered at different junctures. Though most actions can be performed by multiple roles, this diagram shows the roles that typically perform certain actions. When the submission is in an editable state (highlighted in yellow below), a member of the protocol team edits it as needed and submits or resubmits it.



Actions and State Transitions

Actions and State Transitions			
In this state…	These roles…	Can perform these actions…	Changing the submission state to…
(No State)	Any registered user	Create a new Safety protocol	Pre-Submission
Pre-Submission	Principal Investigator or PI Proxy	Submit	Specialist Review

Actions and State Transitions			
Specialist Review	Safety Specialist	Send to BSO Review	BSO Review
		Send to Member Review	Member Review
		Approve Submission (Admin)	Post-Review
	Safety Specialist, Safety Administrator	Request Clarification by Specialist	Clarifications Requested (Specialist Review)
	Safety Specialist	Submit Specialist Review	Committee Review
Clarification Requested (Specialist Review)	Principal Investigator or PI Proxy	Submit Response	Specialist Review
BSO Review	Biosafety Officer	Submit Biosafety Risk Assessment	Specialist Review
		Request Clarification by BSO	Clarification Requested (BSO Review)
Clarification Requested (BSO Review)	Principal Investigator or PI Proxy	Submit Response	BSO Review
Member Review	Committee Member, Safety Specialist, Safety Administrator	Submit Member Review (the state does not change to Specialist Review until all the reviewers submit their review)	Specialist Review
	Committee Member	Request Clarification by Member	Clarification Requested (Member Review)
Clarification Requested (Member Review) This can be configured in settings by Site Manager	Principal Investigator or PI Proxy	Submit Response	Member Review
Committee Review	Safety Specialist, Safety Administrator, Committee Chair	Submit Committee Review	Post-Review

Actions and State Transitions			
Clarification Requested (Committee Review)	Principal Investigator or PI Proxy	Submit Response	Committee Review
Post-Review	Safety Specialist, Safety Administrator	Forward Letter for Review(a determination letter must be prepared beforehand)	Chair Letter Review
	Committee Chair, Safety Specialist, Safety Administrator	Send Letter (a determination letter must be prepared beforehand)	A state reflecting the committee decision entered during the Submit Committee Review action: Approved Approval Withheld Modifications Required Deferred
Chair Letter Review	Safety Specialist, Safety Administrator, Committee Chair	Send Letter (a determination letter must be prepared beforehand)	A state reflecting the committee decision entered during the Submit Committee Review action: Approved Approval Withheld Modifications Required Deferred
	Committee Chair	Request changes to Letter	Post-Review
Modifications Required	Principal Investigator or PI Proxy	Submit Response	Modifications Review
Modifications Review	Safety Specialist	Send to Member Review	Modifications Review by Member
		Request Clarifications by Modifications Reviewer	Modifications Required
		Verify (Admin)	Post-Review
Modifications Review by Member	Committee Member	Submit Modifications Review Findings	Specialist Review (if committee review is required) Post-Review (if committee review is not required)
Approval Withheld	Principal Investigator or PI Proxy	Submit Response	Specialist Review

Actions and State Transitions			
Approved	Principal Investigator, Protocol team members	Request Closure	Closure Requested
	Safety Specialist, Safety Administrator	Suspend	Suspended
		Close Protocol	Closed
Closure Requested	Safety Specialist, Safety Administrator	Close Protocol	Closed
		Request Clarification from Specialist	Clarification Requested (Closure Requested)
Clarification Requested (Closure Requested)	Principal Investigator or PI Proxy	Submit Response	Closure Requested
		Withdraw Closure Request	Approved
Deferred	Principal Investigator or PI Proxy	Submit Response	Specialist Review
All states before Post-Review	Assigned Principal Investigator, Protocol team members	Discard	Discarded
All states before Post-Review except Pre-Submission	Assigned Principal Investigator, Protocol team members	Withdraw	Pre-Submission

Navigation and Basic Tasks

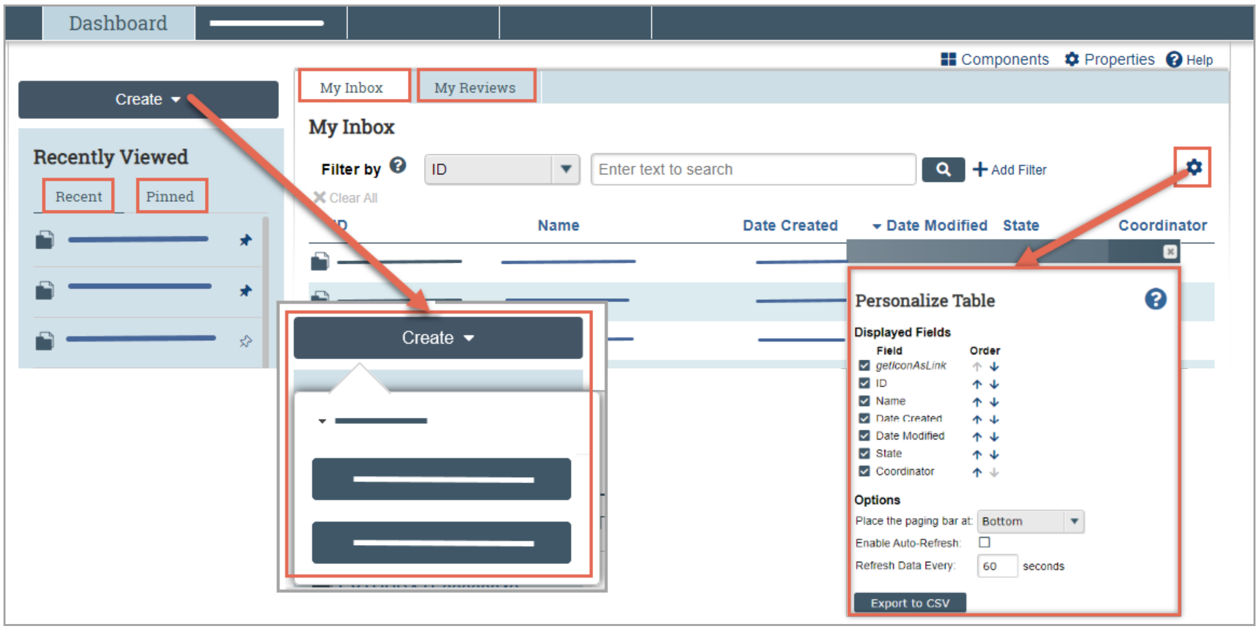
When you first log in, you will be on the Dashboard. This topic lists where to find Safety protocols and the basic tasks you will perform.

To find key items

From your Dashboard, you will see:

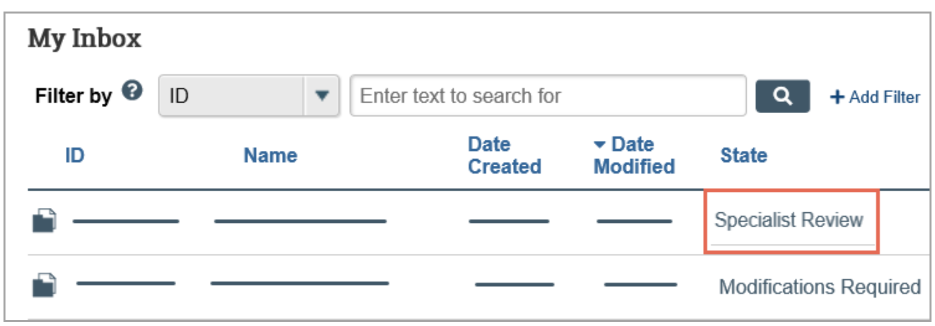
- **My Inbox:** Items that require you to take action.
- **My Reviews:** Items assigned to you to review. These are a subset of the items in My Inbox.
- **Create menu and buttons:** Actions you can perform. The menu will not show if you do not have access to any buttons.

- **Recently Viewed:**
  - **Recent**: The last several items you viewed. Scroll through this list to find an item you worked on recently.
  - **Pinned:** You can pin the items in Recently Viewed section for quick and easy access. This is where those pinned items are listed.
- **Personalize Table:** You can alter the tables displayed on the dashboard by using the Personalize Table gear icon.



To identify what action is needed

1. Review the state of submissions in My Inbox.
   The state gives a clue as to what to do next. For example, “Specialist Review” means the submission is currently ready for review or being reviewed by a Safety specialist.



To open a submission

- From My Inbox, click the submission name.
  The submission workspace opens.

To view submission history

1. From the submission workspace, click the **History** tab.
   The history lists the activity taken on a submission, including any comments, attachments, or correspondence added.

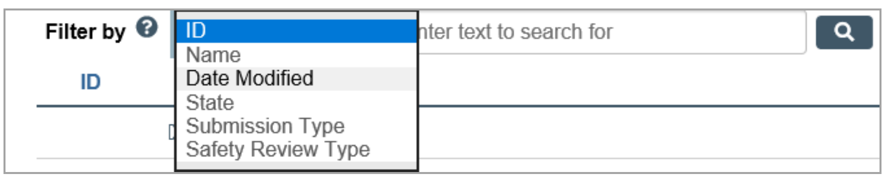
To find previous submissions

1. From the Top Navigator, click **Safety**.
2. Click the appropriate tab to see all of your submissions:
   - **In-Review**: All submissions undergoing Safety committee review
   - **Active**: All approved submissions
   - **Archived**: All discarded and closed submissions
   - **Suspended or Lapsed**: All submissions that have been suspended or whose continuing review due date has passed
   - **All Submissions**: All submissions, in any state

To filter data in a table

Many pages contain tables that you can filter to show only specific records. You may also need to filter a list of selection options, so you can find the correct ones to select.

1. Select the column to filter by.



2. Type the beginning characters for the items you want to find. You can also type a % symbol as a wildcard before the characters. For example:
   - 71 shows all items beginning with 71
   - %71 shows all items containing 71
3. For a list of operators you can type in the search box and press Enter or, click the Search icon.
4. Click **Go** to apply the filter.
5. To combine multiple filter criteria, click **Add Filter**.

Search the System Using Key Words

You can also search for submissions using key words. For example:

- Submission involving a specific PI.
- Submissions that involve a certain incident.

Note: The system will only return those items you have permission to view.

To search for submissions

1. From the Top Navigator, click **Safety**.
2. In the Search field, type your search criteria. You can use the following operators:
   - **And**: All submissions undergoing Safety committee review.
   - **Or**: Finds at least one of the specified words.
   - **Not**: Excludes the specified word.
   - **Asterisk (*)**: Wildcard character. Finds part of a word.
   - **Quotation marks**: Finds the exact phrase.
3. Press **Enter** or click the magnifying glass to perform the search.

Assign a Safety Specialist

After the PI submits a protocol or follow-on submission for review, it appears in the Inbox of all Safety specialists for the administrative office specified in the protocol. The first step is to assign a specialist to handle the submission. Any user with the specialist or administrator role can do this.

To assign safety specialist

1. From My Inbox, click the submission name.
   Alternatively, click the submission name in the In-Review submission tab.
2. From the submission workspace, click **Assign Specialist** on the left.

3. Select a Safety specialist from the list and then click **OK**.

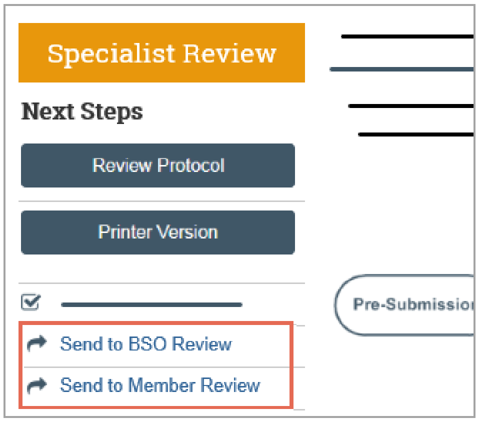
Note: You can also assign a specialist on the page that appears when you submit a specialist review or administratively approve a submission. When the submission enters a state requiring specialist attention, it appears only in the assigned specialist's Inbox.

Initiate a BSO or Member Review

As the assigned specialist, you might decide that you want a review performed by the Biosafety Officer (BSO) or a particular committee member.

To send submission to BSO or Member Review

1. From My Inbox, click the submission name.
   Alternatively, click the submission name in the In-Review submission tab.
2. From the submission workspace, click **Send to BSO Review** or **Send to Member Review**.



3. Select a Biosafety Officer or one or more committee members.
4. Click **OK**.
   The submission returns to the assigned specialist's inbox.

Send Submission into Committee Review

As the assigned specialist, you can send a submission that is in the Specialist Review state into committee review. Alternatively, you can send the submission to a biosafety officer or committee member for review first, or approve it administratively instead.

To submit specialist's review to the safety committee

1. From My Inbox, click the submission name.
   Alternatively, click the submission name in the In-Review submission tab.
2. From the submission workspace, Click **Submit Specialist Review**.

3. Select a committee meeting.
4. If not already assigned, select yourself or another specialist to handle this submission.
5. Select **Yes** to indicate that the review is complete.
6. Add any comments or supporting documents.
7. Click **OK** to send the submission to committee review.

Submit the Committee Review

Once the Safety committee has reviewed a submission and determined how to handle it, a specialist typically records the committee's decisions by submitting the committee review.

Prerequisites for this task

- The submission is in the Committee Review state.
- You are logged in as the Safety administrator, Safety specialist or committee chair role.

To submit the Committee Review

1. Open the submission.
2. Click **Submit Committee Review**.

3. Select your determination.
4. The last day of the continuing review period populates automatically. However, if necessary, you can modify this date.
5. If the committee:
    a. **Approved the submission**: Select the approval date (typically the committee meeting date).
    b. **Withheld approval or required changes:** Type those details in the **Identify**... text box.
6. If desired, you can also document the committee's vote, supply additional comments, and attach supporting documents.
7. Click **OK** to submit the committee review.

The submission enters the Post-Review state, which enables you to notify the PI of the review decision.

Approve a Submission Administratively

If you determine a committee review is not necessary, as the assigned specialist, you can administratively approve a submission that is in the Specialist Review state, sending it directly into Post-Review state.

To approve the submission

1. From My Inbox, click the submission name.
   Alternatively, click the submission name in the In-Review submission tab.
2. After any requested reviews have been submitted, in the submission workspace, click **Approve Submission (Admin)**.

3. If not already assigned, select yourself or another specialist to handle this submission.
4. Select the committee to acknowledge that the submission has been approved.
5. The last day of the continuing review period populates automatically, but you can override this date.
6. Select the date you are approving the submission.
7. Add any comments or supporting documents and click **OK**.

The submission enters the Post-Review state, which enables you to manage the approval letter.

Edit a Submission as Safety Staff

Depending on your institution's settings, Safety staff (Safety specialist and Safety administrator) are able to edit protocols and follow-on submissions on behalf of the protocol team. A Safety setting, as described in the *Safety Deployment Guide*, must be enabled to allow this.

If the setting is enabled, Safety staff members can make any change to submissions submitted to their administrative office in any state up until it is approved. For example, when you are completing the pre-review process and notice a small inconsistency in the submission, your Safety system allows you to edit the submission. You can add a comment to the submission detailing the changes and notify the protocol team members.

To edit a submission as Safety staff

1. From My Inbox, click the submission name you want to edit.
2. From submission workspace, click **Edit Protocol** (or **Edit Amendment** or **Continuing Review**) and make the changes.
3. Notify the PI and protocol team as follows:
   a. Click **Add Comment** and describe the change you made in the Comments box.
   b. Select the roles to be notified of the change.
   c. Click **OK** to add the comment and send the notification.

Manage the Determination Letter

When a submission enters the Post-Review state, Safety staff or the committee chair can prepare and send the determination letter. If a member of the Safety staff prepares the determination letter, it can be sent to the committee chair for review.

When a submission moves to the final state (e.g., approved) and it is discovered that a correction needs to be made to the sent letter (e.g., the approval letter), Safety specialists and Safety administrators can upload a modified version of the letter document, prepare and send the revised letter, and the protocol team receive an email indicating that the letter has been updated.

To prepare the determination letter

1. From My Inbox, click the submission name.
2. From the submission workspace, click **Prepare Letter**.
3. To create a letter from a template:
   a. Select a letter template.
   b. Click **Generate**.
4. Alternatively, click **Upload**, then navigate to a prepared document.
5. Click **OK**.

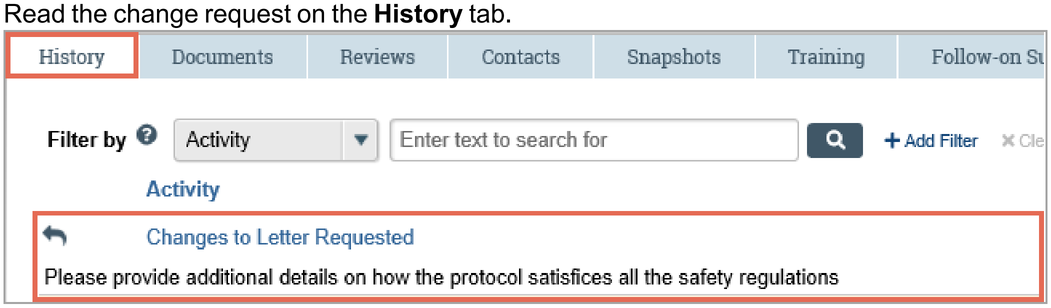
To have the letter reviewed

1. Click **Forward Letter for Review**.
2. Click **OK**.

The state changes to Chair Letter Review and the submission appears in the chair's Inbox.

To make any requested changes

1. Read the change request on the **History** tab.



2. Click the letter name to open.
3. Revise the letter and save it.
4. click **Upload**, then navigate to a prepared document.
5. Click **OK**.
6. For another review see To have the letter reviewed.

To send letter to the PI (when ready)

1. Click **Send Letter**.
2. Click **OK**.

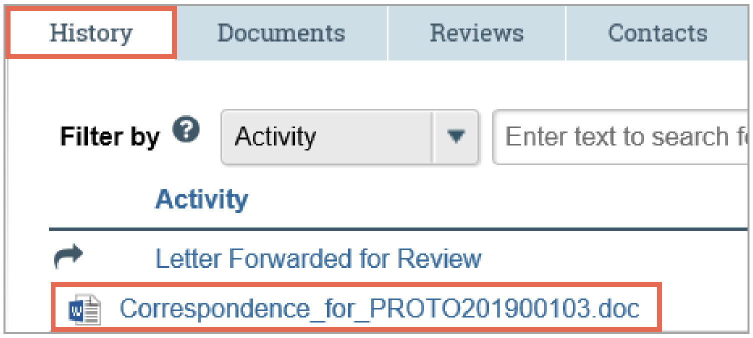
Depending on the determination selected in Committee Review, the state changes to Approved, Modifications Required, Approval Withheld or Deferred.

Review the Determination Letter

As committee chair, you might receive determination letters to review before they are sent.

To review the determination letter

1. From My Inbox, click the submission name.
2. On the History tab, under Letter Forwarded for Review, click the name of the letter.



3. On the resulting query, click **Open**.
4. Review the letter.

To request for changes

1. From the workspace, click **Request Changes to Letter**.
2. Describe the requested changes and click **OK**.
   The state changes to Post-Review and the submission reappears in the specialist's Inbox.
3. From the submission workspace, click **Send Letter**.
4. Click **OK**.

Depending on the determination selected in Committee Review state, the state changes to Approved, Modifications Required, Approval Withheld or Deferred.

To alternatively make changes yourself

1. Review the determination letter. See To review the determination letter.
2. Make the needed revisions to the determination letter and save it.
3. Click **Prepare Letter**.
4. Click ellipsis and then **Upload Revision**.
5. Upload the revised letter and then click **OK**.
6. Click **OK** on the Prepare Letter page.
7. From the submission workspace, click **Send Letter**.
8. Click **OK**.

Verify Required Modifications

When a PI resubmits a protocol with modifications that the Safety committee required for approval, the submission moves to the Modifications Review state. The Safety specialist then verifies the modifications.

To view and comment on modifications

1. From My Inbox, click the submission name.
   Alternatively, click the submission name in the In-Review submission tab.
2. From the submission workspace, click **Review Protocol**.
3. On the Left Navigator of the SmartForm, each step with a modification is indicated by an Edit icon.
4. Click the name of the step and view the changes made.
   - For differences, such as a new selected value for a check box or an added attachment, the differences are only outlined in a callout box below the step.
   - For text fields, new text is highlighted and the old content can be found in the callout box.

5. To comment on a modification:
    a. Click the Note icon. If there were any notes previously added to the step, you will see them here along with the Change History.
    b. Type your note in the text box.
    c. Select Response Required and/or attach files if needed.
    d. Click **OK** and then **Close.**

    Note: Safety staff, officers and committee members can see the identity of reviewer notes author while viewing the reviewer notes. If your institution's setting allows, they can also edit, delete, or resolve the reviewer notes by other authors. PI and protocol team members cannot see the author of reviewer notes.

6. Select **Above section has been reviewed** check box when you have finished reviewing that section on the SmartForm to help you track your review progress.
7. In the Modifications Review state, the Safety specialist verifies the modifications then performs tasks as described below.
    Based on your assessment, perform one of the following three tasks from the protocol workspace:
    - **Send to Member Review**: Request committee member review.
    - **Request Clarification by Modifications Reviewer**: Request clarification or changes.
    - **Verify (Admin)**: Send the submission to Post-Review.

To send to member review

1. From the submission workspace, click **Send to Member Review**.
2. Select one or more committee members.
3. Click **OK**.
    The state changes to Modifications Review by Member.

To request clarification by modifications reviewer

1. From the submission workspace, click **Request Clarification by Modifications Reviewer**.
2. Describe the required changes.
3. Click **OK**.
    The state changes to Modifications Review by Member.

To verify (Admin)

1. From the submission workspace, click **Verify (Admin)**.
2. Click **OK**.
    The determination changes to “Approved,” and the submission returns to **Post-Reviewer**.
3. Click **OK**.
    The state changes to Modifications Review by Member.

Set Up Ancillary Reviews

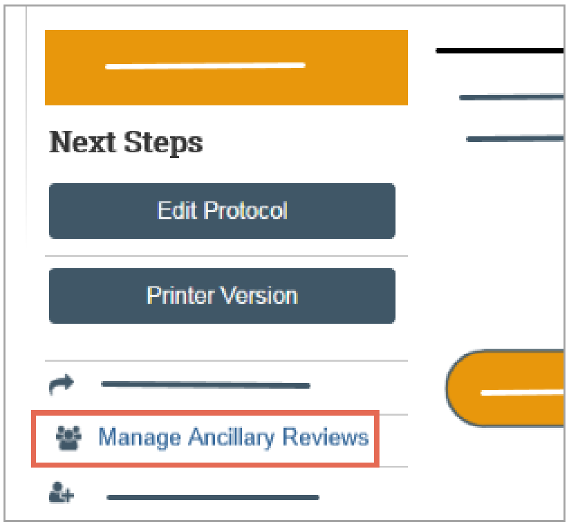
Principal Investigators can set up ancillary reviews when a submission is in any editable state, and Safety staff can do so anytime from submission creation through Post-Review. All ancillary reviewers receive notifications stating they have been assigned. In addition, the submission appears in the inbox of each required reviewer and remains there until they accept or reject the submission. If a protocol is in the Pre-Submission state, notifications and updates to the inbox do not occur until the protocol is submitted.

If an error message displays in an activity, stating that "All required ancillary reviews must be completed and accepted before executing this activity," either of the following actions can resolve the situation:

- The reviewer completes the ancillary review and accepts the submission.
- A Safety staff member overrides the blocking of ancillary review. For more information, see Override Blocking of Ancillary Reviews.

To set up an ancillary review

1. From My Inbox, click the submission name.
   Alternatively, click the submission name in the In-Review submission tab.
2. From the submission workspace, click **Manage Ancillary Reviews**. (Depending on the state of the submission, it may be farther down in the list.)



3. Click **Add**.
4. (Optional) Type comments and upload supporting documents.
5. Select reviewers by organization or by person.
6. (Optional) Select the type of review.
7. Select whether a review is optional or required for the specified reviewers.
8. In Add Ancillary Review, click **OK** or **OK and Add Another**.

   When you finish adding reviewers, click **OK** in Manage Ancillary Reviews.

The newly added reviewers receive notifications, and the submission appears in the inbox of each required reviewer.

To override blocking of ancillary reviews

If an ancillary reviewer does not accept a protocol or complete a required ancillary review, the submission is blocked from moving forward.

1. From My Inbox or one of the tabs on the appropriate Safety page, click the name of the submission for which you want to override the ancillary review.
2. In the protocol workspace, click **Manage Ancillary Reviews**.
3. Select the **Yes** option for the statement 'Allow the workflow to proceed despite incomplete required reviews'.

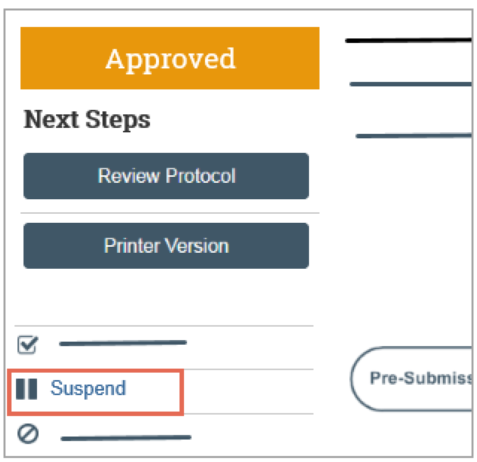
4. Provide the rationale for the override, then click **OK**.

Suspend a Protocol

In some circumstances, such as a safety violation, the committee might vote to suspend all activity on a project until the problem is resolved. In such cases, a specialist or the Safety administrator suspends the approved submission.

To suspend the protocol

1. From My Inbox, click the submission name.
   Alternatively, click the submission name in the Active submissions tab.
2. From the submission workspace, click **Suspend**.



3. Type the reason for the suspension.
4. Select the effective date of the suspension (must be the present date or a date in the past).
5. (Optional) Type additional comments or upload supporting documents.
6. Click **OK**.

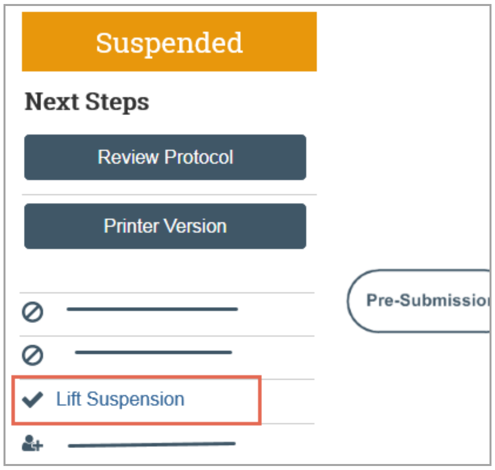
The submission changes to the Suspended state.

Lift Suspension from a Protocol

When the situation that warranted suspending a protocol has been addressed sufficiently to resume the project, the specialist or Safety administrator can lift the suspension.

To lift the suspension

1. From My Inbox or the Suspended or Lapsed tab, click the name of the submission whose suspension you want to lift.
2. From the submission workspace, click **Lift Suspension**.



3. Type a description of the corrective action taken that justifies lifting the suspension.
4. Select the date the suspension ended (must be the present date or a date in the past).
5. (Optional) Type additional comments or upload supporting documents.
6. Click **OK**.

The protocol returns to the Approved state.

Note: If a submission passes the last day of the continuing review period while suspended and you lift the suspension, then the submission enters the Lapsed state instead of Approved.

Tag Submissions

As a Safety staff member, you can add tags or keywords, to protocols and follow-on submissions so that you can later report on those submissions. For example, you could tag submissions with "follow-up inspection" to identify submissions that require additional action.

You can associate tags to submissions in any state.

Note: You must have Safety Data Manager privileges to create or update the list of tags that can be associated with submissions.

To tag a submission

1. From My Inbox, click the name of the submission to open it.
2. Click **Manage Tags**.
3. Under Associate Tags, start typing the name of the desired tag or click the ellipsis.
4. Select tags from the list and click **OK**. If you want to use a tag that is not in the list, contact your Data Manager to add it.
5. Click **OK** to associate the tags with the submission.

Tip: You can find the tagged submissions by searching for the tag text in the search box on the Safety Submissions page

Generate a Report of Submissions with Tag

As a Safety staff member, you can run a Submissions with Tags standard report and use the Change Parameters feature to filter the report to show only submissions that have specific tags.

To generate a report of submissions that have certain tags

1. Click **Safety** on the Top Navigator then click **Reports** on the Sub-Navigator.
2. On the **Standard Reports** tab, click the **Submissions with Tags** report link.
3. In the Filter by area, click the drop-down menu and select **Safety Tags**.
4. Type the beginning characters for the tag you want to find. You can also type a % symbol as a wildcard before the characters. Examples:
   - 71 shows all items beginning with 71
   - %71 shows all items containing 71
5. Click the search icon  to apply the filter. See Filter and Sort Data on page 22 for more details.
   A list of submissions with the searched tag displays.

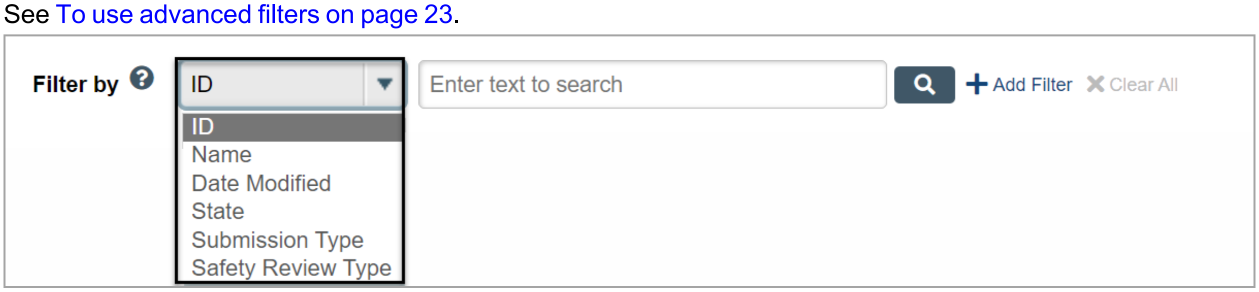
Filter and Sort Data

Many pages contain tables that you can filter and sort to help you find the data you want.

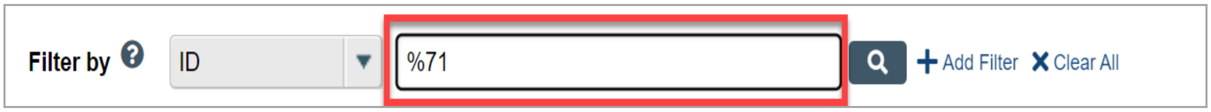
- Filtering reduces the list to show the data that meets the criteria. The advanced filter lets you combine multiple filter criteria together.
- Sorting displays the data in ascending or descending order by a particular column.

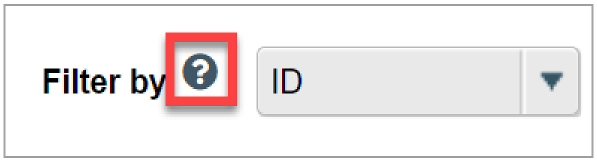
To filter data

1. Select the column to filter by from the drop-down menu. The menu lists only the columns you can filter by.
   Note: To combine multiple filter criteria, such as, ID, Name, and Date Created, use the advanced filters. See To use advanced filters on page 23.



2. In the text box, type the beginning characters for the items you want to find. If you do not know the beginning characters, type a % symbol as a wildcard before the characters. Examples:
   - 71 shows all items beginning with 71
   - %71 shows all items containing 71 in any position



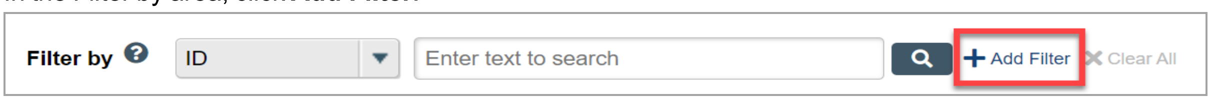
> **Tip**: For examples and a list of operators you can use, click the Help icon.
>
> 
>

3. Click the magnifying glass to apply the filter.
   The table shows only those rows that are an exact match.

> **Tip**: If you do not see the expected items in the list, click Clear All in the Filter By area to remove the filter.

To use advanced filters

1. In the Filter by area, click **Add Filter**.



2. Enter filter criteria as explained in the previous section. See **To filter data**.
3. To add more criteria, click **Add Filter** once more.
4. Click the magnifying glass to apply the filter.
   The table shows only those rows that match all the filter criteria.

To sort data

1. Click the column header you want to sort by.
2. Click it a second time to reverse the sort order.
   The arrow indicates the column by which the data is sorted and the sort order, either ascending (up arrow) or descending (down arrow).

Note: If the column header is not a link, you cannot sort by that column.

For more information on finding records and other information, see Navigation and Basic Tasks .

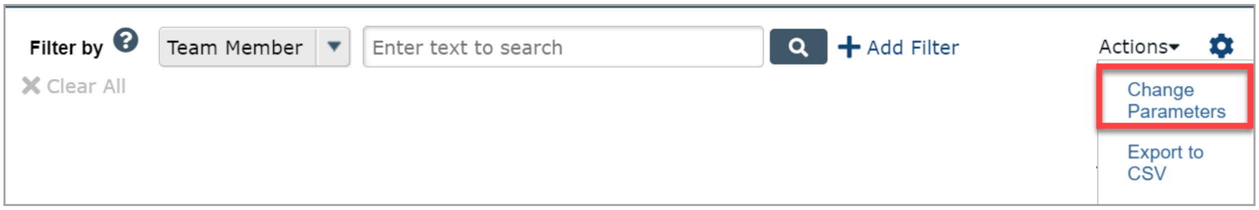
Change the Criteria of the Report

For some reports, you can change the criteria used to create the report before you apply additional filters or change the sort order. Many pages contain tables you can filter and sort to help you find the data you want.

Note: For details on using Advanced Reports, see the Advanced Reports Guide.

To change the criteria of the report

1. On the right of the Filter by area, click **Actions**, and then click **Change Parameter**.



2. Change the report criteria field values as needed. Typically, multiple criteria rows (see example 2) are treated with an "**and**" between them. That is, the report shows items that meets the criteria 1 **and** criteria 2.

> **Tip**: For a list of the operators, you can use in the parameter criteria, click the Help icon.

- **Example 1:** Shows all projects where Project Type is Safety Submission **and** where State ID **is not** in DRAFT state (!= means the field is not the specified value).

Field	Comparator	Value
Associated Project.Type	=	_ClickSafetySubmission
Associated Project.Project State.ID	!=	Draft

- **Example 2:** Shows projects that expires in the next 90 days, that is, the expired date must be before or on "today plus 90 days" **and** the expired date must be today or later. For these fields, you can select different dates using the calendar.

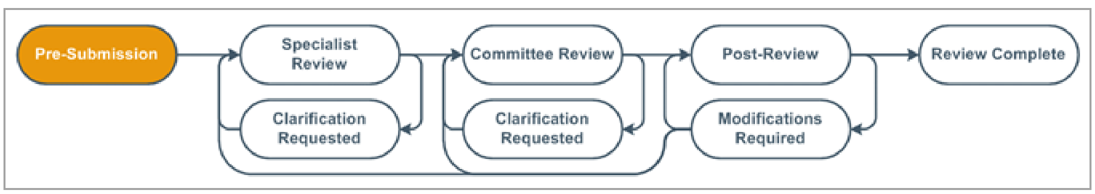
Field	Comparator	Value
Date Expired	<	Today plus 90 day(s)
Date Expired	>=	Today

3. Click **OK.**

Overview of Safety Incidents

Huron Safety enables any registered user to create an incident report describing a safety incident. The Safety staff, officers, and corresponding committee members can review the incident as appropriate, taking corrective action where necessary.

- Any registered user can create an incident from My Inbox or from the workspace of an approved Safety protocol. The user completes a short form or a long form. The long form is reserved for those creating incidents from the protocol workspace and Safety staff (specialists and administrators), committee members, and Safety officers.
- The person who created the incident or a Safety staff member or officer must submit it. An incident created from My Inbox using the short form cannot be edited or submitted by its creator. A Safety staff member or officer must edit the incident on behalf of the creator to include all required details and then submit it. Once submitted, the state changes to Pre-Review.
- In any state, the Safety staff or officer can request clarification from anyone, potentially making unique, simultaneous requests to multiple parties. The Safety staff or officer can also assign responsible parties for corrective action, although the parties are not notified until the incident moves to the Pending Corrective Action state.
- During Pre-Review, the Safety staff or officer reviews the incident and determines whether committee review is needed, which could move the incident to the Assigned to Meeting state. If committee review is not needed, they can send the incident to a final state of No Action.
- In addition, the Safety officer can specify the corrective actions needed and move the incident to the Pending Corrective Action state.
- During Assigned to Meeting, the committee has the same options as were available in the Pre-Review state.
- During Pending Corrective Action, the Safety staff or officer can update the action plan if needed. The responsible parties, Safety staff, or officer can also indicate that the action plan is complete, moving the incident to the Corrective Action Completed state.
- During Corrective Action Completed, the Safety staff and officers can confirm that the plan was completed, which moves the incident to the Complete state. Alternatively, they can update the action plan, or they can request clarification to move the incident back to the Pending Corrective Action state.



Request Clarifications on an Incident

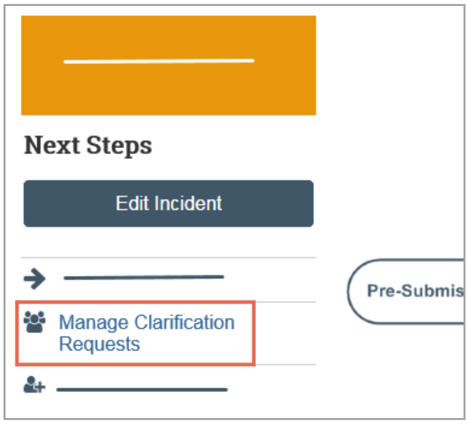
From any state, it is possible to request clarifications regarding an incident. You can do this by making one or more requests to multiple users. Users you select are automatically added to the guest list so they can view the incident.

Prerequisites for this task

- You are Safety staff for the assigned admin office or a Safety officer matching the incident type (e.g., chemical officer/chemical incident).

To make requests

1. Open the incident workspace.
2. Click **Manage Clarification Requests**.

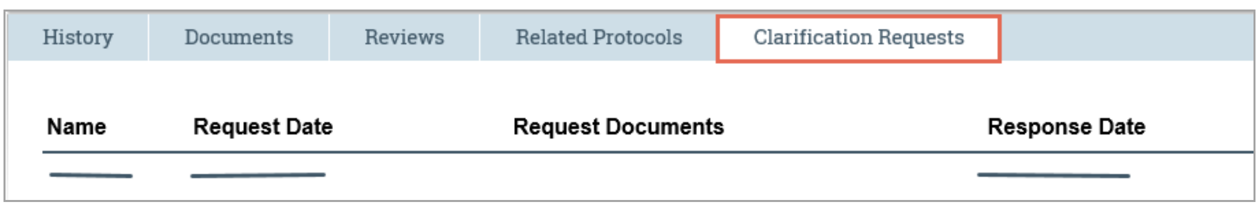


3. Click **Add**.
4. Select a person.
5. Type a request.
6. If you are done, click **OK**. Otherwise, click **OK and Add Another** to make another request to the same or a different person.
7. When you are finished adding requests, click **OK**.

Notifications are sent and the selected respondents are added to the guest list for the incident.

To view requests and responses

1. In the incident workspace, click the **Clarification Requests** tab.



To update or cancel requests

1. In the incident workspace, click **Manage Clarification Requests**.
2. To update a request:
   - Click **Update** next to the request.
   - Make the changes and click **OK**.
3. To cancel a request, click **Delete**.
4. Click **OK** to save your changes.

Handle an Incident in Pre-Review

From the Pre-Review state, a Safety staff member or Safety officer can assign an incident to a meeting for committee review or mark the incident as needing no further action. A Safety officer can also determine that corrective action is required and start the corrective action process.

To assign an incident to a meeting

1. Open the incident workspace.
2. Click **Assign to Meeting**.
3. Select a meeting, add any comments and attachments, and click **OK**.

To report the incident as no action

1. In the incident workspace, click **Report as No Action**.
2. Select the committee that will see the incident on an upcoming meeting agenda as an acknowledgment item.
3. Add any comments and attachments, and click **OK**.

To require corrective action

You must be a Safety officer to do this.

1. In the incident workspace, click **Require Corrective Action**.
2. Select the committee that will see the incident on an upcoming meeting agenda as an acknowledgment item.
3. Specify whether this incident requires reporting.
4. Describe the action plan and/or attach a description of the plan.
5. Add the people responsible for carrying out the plan.
6. Click the Calendar icon and select a due date for completion of the plan.
7. Add any comments and documents, and click **OK**.

The responsible parties are notified.

Record the Committee Decision for an Incident

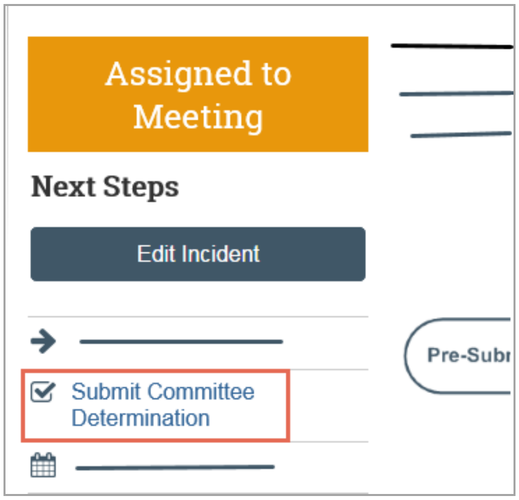
Once the Safety committee has reviewed an incident and determined how to handle it, a specialist typically records the committee’s decisions.

Prerequisites for this task

- The incident is in the Assigned to Meeting state.
- You are a Safety staff member or officer.

To record the review decision

1. From the incident workspace, click **Submit Committee Determination**.



2. Select the determination.
3. If the committee chose Corrective Action Required:
   a. Specify whether this incident requires reporting.
   b. Describe the action plan and/or attach a description of the plan.
   c. Add the people responsible for carrying out the plan.
   d. Click the Calender icon and select a due date for completion of the plan.
4. If the committee chose No Action, skip to the next step.
5. If desired, you can record the committee’s vote, supply additional comments, and attach supporting documents.
6. Click **OK** to submit the committee review.

The submission enters the Pending Corrective Action state, and email notifications are sent to the responsible parties regarding the required actions.

Review Corrective Actions Taken

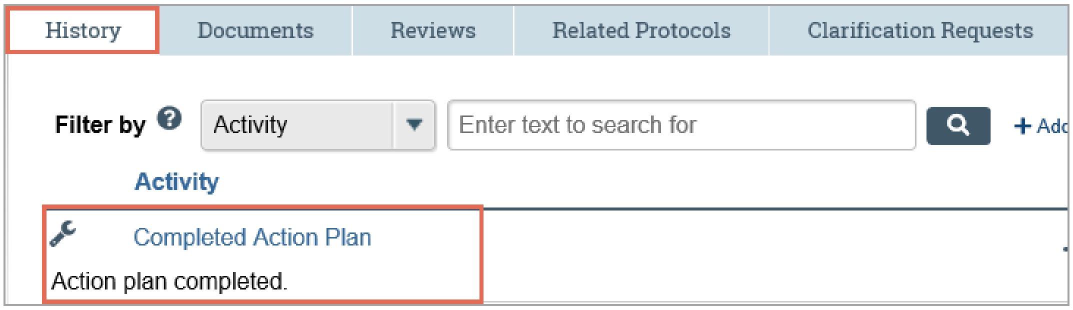
After a Safety staff member, or Safety officer has used the Action Plan Complete activity to declare the plan completed, the actions taken need to be reviewed and confirmed. After reviewing the action plan and the actions taken from the Corrective Action Completed state, the Safety staff member or Safety officer can indicate that the plan is completed or request clarifications to move the incident back to the Pending Corrective Action state.

To review the action plan

1. From the incident workspace, click the **Reviews** tab.
2. Read the action plan.
3. Open any action plan documents by clicking the links.

To view the response to the action plan

1. Click the **History** tab.
2. Locate the item called **Completed Action Plan** in the history log.



3. View any comments from the responsible parties.
4. Open any response documents by clicking the links.

To indicate whether the action is complete

1. From the incident workspace, click **Submit Confirmation**.
2. Indicate whether the action plan was completed as required:
   a. If completed, select **Yes**. The incident will transition to Complete when you click **OK**.
   b. If not completed, select **No** and enter clarifications. The incident will transition back to Pending Corrective Action when you click **OK**.
3. Add any comments and documents, and click **OK**.

Overview of Safety Inspections

Huron Safety enables Safety officers and Safety staff to schedule an inspection of research facilities or practices, record findings, perform corrective action, and add findings to Safety committee meeting agendas.

A Safety officer or Safety staff member creates inspections from My Inbox. The officer or staff member defines the inspection, including:

- The type of inspection
- When and where it will be carried out
- Who will be the inspectors (must be a Safety officer)
- The Principal Investigators of projects conducted at the facility to be inspected

The inspection is editable in any state by Safety staff members from the assigned administrative office and by Safety officers corresponding to the type of inspection (for example, users with the role Radiation Safety Officer for radiation safety inspections). In addition, in any state, a Safety officer or staff member can associate an inspection with any other inspections (also in any state).

After the inspection is created, it is in the Pending Inspection state. The person who created it or a Safety staff member or officer must activate it, changing the state to Active Inspection.

When satisfied with the inspection details, the Safety officer or staff member completes it. This includes selecting the specific committee meetings to be informed of this inspection's findings, and confirming that this inspection is complete. This changes the state to Inspection Complete.

The recorded findings will appear as acknowledgment items on the agendas of the selected committee meetings, provided they are scheduled to convene in the next 60 days, and they are in the Scheduled or Agenda Sent states. Safety officers and staff can continue to update inspection findings even after the completion.

Create and Activate an Inspection

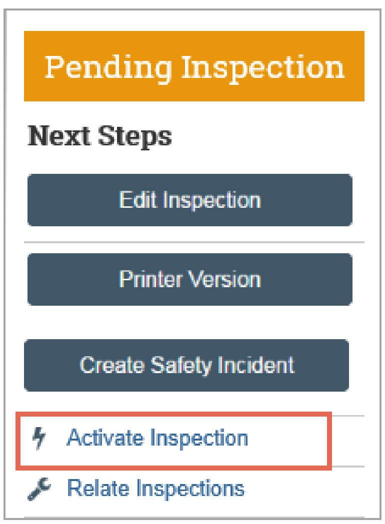
Safety officers and Safety staff can create an inspection and activate it. You can create findings only after the activation.

To create and activate an inspection

1. From the Dashboard, click the **Create** menu and then select **Create Safety Inspection**.
2. Supply basic inspection information on the first page.
   The inspection types you select determine the types of Safety committees you will be able to select. You can select multiple inspection types.
3. When you have completed this page, click **Continue**.
4. On the next page, enter the inspection details.
   When you add committees, only committees appropriate for the inspection types selected previously appear. When you add inspectors, only Safety officers appear.
5. When you have completed this page, click **Finish**.

To activate the inspection

1. In the inspection workspace, click Activate Inspection.



2. Click **Yes** for 'Is this inspection ready to be activated?' (Optionally) You can add a comment and attach supporting documents.
3. Click **OK**.

The inspection transitions to the **Active Inspection** state.

Record a Finding

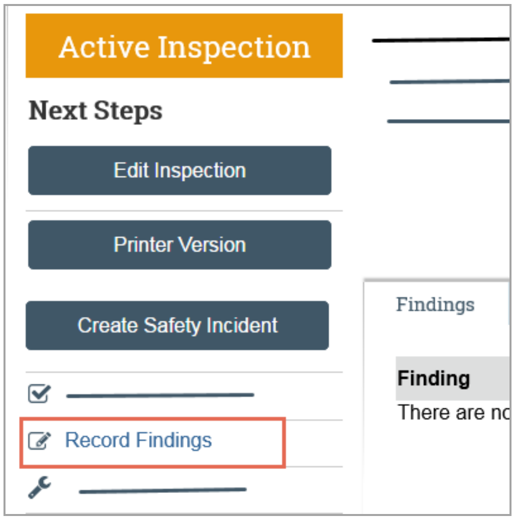
Once an inspection is in the Active Inspection state, Safety officers and Safety staff can record findings for committee review. You select findings from a predefined list. You can record multiple findings in one inspection, but each finding is included separately in committee meeting agendas.

To select a finding

1. If the desired inspection is not in your Inbox:
   a. Click the **Inspections** link.
   b. Click the name of the desired active inspection.

> **Tip:** In case of long search result list, you can use the filter feature to find a specific active inspection.

2. In the inspection workspace, click **Record Findings**.



In the Add Safety Inspection Finding dialog box, search for the desired finding and select it. Alternatively, click **Select** to show the list of predefined findings.

To define any corrective action

1. If corrective action is required, select **Yes** for Corrective action required? and complete the additional questions that appear for describing it.
2. When you have completed the page, click **OK** and **Add Another**, or **OK** to stop adding findings.
3. Add any supporting documents if applicable and then click **OK**.

The findings you have recorded appear on the Findings tab of the inspection workspace, and will appear as acknowledgments on the agenda of an upcoming Safety committee meeting.

Complete an Inspection

Completing an inspection involves selecting Safety committee meetings to discuss your findings. In the process, you can also make changes to the findings list and access meeting details.

To select meetings to discuss findings

1. If the desired inspection is not in your Inbox:
   a. Click the **Inspections** link.
   b. Click the name of the desired active inspection (With long lists, locate it using the filter feature).
2. In the inspection workspace, click **Complete Inspection**.
3. On the Complete Inspection dialog box, search for the desired Safety committee meeting and select it. Alternatively, click **Add** to display the meetings list.

4. To view a selected meeting, and confirm or decline attendance, click the meeting name.
5. If necessary, add, update or delete findings to be discussed by the selected meetings.
6. (Optional) Add comments and supporting documents.

To confirm the inspection is complete

1. Select **Yes** for 'Are you ready to complete this inspection?'
2. Click **OK**.

The inspection transitions to the Inspection Complete state. Summaries of the listed findings are added to the agendas of the selected committee meetings as items to be acknowledged.

Track and Manage Training

The Safety Training Coordinator ensures that all Safety members (including non-affiliated community members) have been adequately trained and the research team has the required training to conduct protocol activities. Follow your institution's policies for designing, developing, and delivering training programs.

The Safety system can help you track and manage training. You must have the user role of Training Coordinator to perform the following activities:

- Add training courses into the Safety system. See Add a Training Course on page 32.
- Upon course completion, update the course with the list of attendees that took the course. See Record Course Completion on page 32.
- Inactivate courses that are no longer active or valid. See Inactivate a Course on page 33.
- Track training deadlines. See Identify Training Deadlines on page 33.
- Remove the person who have competed or didn't take the course. See Remove a Person from a Course on page 33.
- Reactivate courses that have been archived. See Reactivate an Archived Course on page 33.

Add a Training Course

You can add new training courses to the Safety system at any time.

To add a training course

1. Click **Safety** on the Top Navigator and then **Training** on the Sub-Navigator.
2. Click **Create Course** on the left side of the training page.
3. Answer the required questions and click **Continue** to move to the next page.
4. (Optional) Enter any other course details and information.
5. On the final page, click Finish on the right.

Record Course Completion

When researchers, Safety committee members, Safety staff (specialists and administrators) or any other personnel have completed a course, you can update the course information to indicate who took it.

To record course completion

1. Click **Safety** on the Top Navigator then **Training** on the Sub-Navigator.
2. On the Courses tab, click the name of the course to open it.
3. Click **Record Course Completion** on the left.

4. Click the ellipsis and select the people who completed the course. click **OK**.
5. (Optional) Add any other course completion details.
6. Click **OK**.

Remove a Person from a Course

When researchers, Safety committee members or Safety staff (specialists and administrators) or any other personnel have completed a course, you can also remove anyone who did not actually take the course.

To remove a person from a course

1. Click **Safety** on the Top Navigator then **Training** on the Sub-Navigator.
2. On the Courses tab, click the name of the course to open it.
3. Click **Remove Course Completion** on the left.
4. Click the ellipsis and select the person you want to remove from the course completion.
5. Click **OK**.

Inactivate a Course

If a course is no longer active or valid, you can inactivate it. Once inactivated, you can no longer record researchers, Safety committee members or Safety staff (specialists and administrators) as having completed the course.

To inactivate a training course

1. Click **Safety** on the Top Navigator then **Training** on the Sub-Navigator.
2. Click the course name to open it.
3. Click **Discontinue Course** on the left side of the course workspace.
4. (Optional) In the Comments box, type your reasons for inactivating the course. You can also attach supporting documents, if appropriate.
5. Click **OK**.
   The course appears on the Archived tab.

Reactivate an Archived Course

If a course has been archived, you can reactivate it.

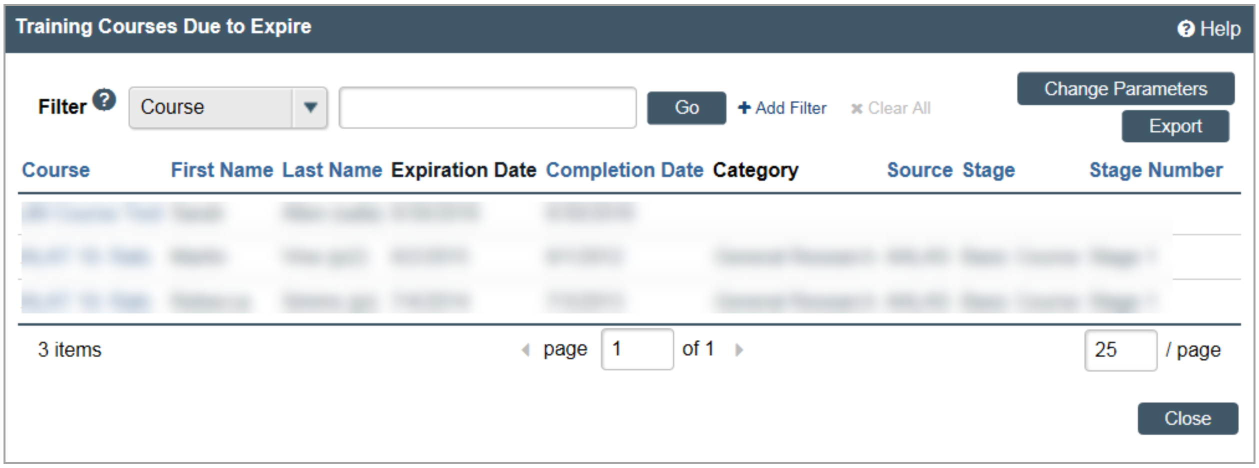
To reactivate an archived training course

1. Click **Safety** on the Top Navigator and then **Training** on the Sub-Navigator.
2. Click the **Archived** tab.
3. Click the course name to open it.
4. Click **Resume Course** on the left of the course workspace.
5. (Optional) In the Comments box, type your reasons for reactivating the course. You can also attach supporting documents, if appropriate.
6. Click **OK**.
   The course appears on the Courses tab.

Identify Training Deadlines

The Safety system comes with standard training reports that show training courses that have expired and training courses due to expire in 90 days.

Both reports list the course, the name of the researchers, Safety committee members, Safety staff (specialists and administrators), and other details about the course, including the expiration date.



Follow your institution's standard operating procedures for dealing with expired training and deadlines.

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