



OSCAR

GUIDE TO FIELD SAFETY CORRECTIVE ACTION REPORT SUBMISSION

The FSCA platform in the Online Safety, Compliance Application and Registration (OSCAR) System allows Medical Device dealers/Registrants to submit FSCA cases when there is a field safety corrective action required for medical devices.

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1 INTRODUCTION

1.1. Accessing OSCAR

Users will require a **Corppass** account to access the OSCAR System.

1.1.1. New Users

For companies accessing OSCAR for the first time, please approach your company's **Corppass Administrator** to log into OSCAR to create OSCAR Admin/User accounts for other company users.

Upon first login, the Corppass Administrator will be required to provide his/her Company Name, Email Address, and Contact Number. After which, a company profile will be created in OSCAR for the company UEN used to login, and an **OSCAR Administrator** will be automatically created under the company profile.

FIGURE 1. OSCAR ADMINISTRATOR ACCOUNT CREATION

OSCAR Admins may then access the Identity Management Module where they can manage users. Please refer to section 1.1.3. for instructions on account creation.

For access to the OSCAR system, company personnel shall approach the company's OSCAR Administrator(s) to create an OSCAR account.

1.1.2. Corppass Administrators for multiple companies

Corppass Administrators administering for more than one company will be required to log in once using each company UEN in order to create separate company profiles in OSCAR. The Company Name, Email address, and Contact Number will be required to be provided upon first log-in using each company UEN. An OSCAR Admin account will then be automatically created under each company profile.

Separate OSCAR user accounts will be required to be created under each company profile in order for the OSCAR users to access OSCAR under the company UEN.

1.1.3. User Roles

Companies may identify personnel to undertake one or more of the following roles.


1. OSCAR Administrator

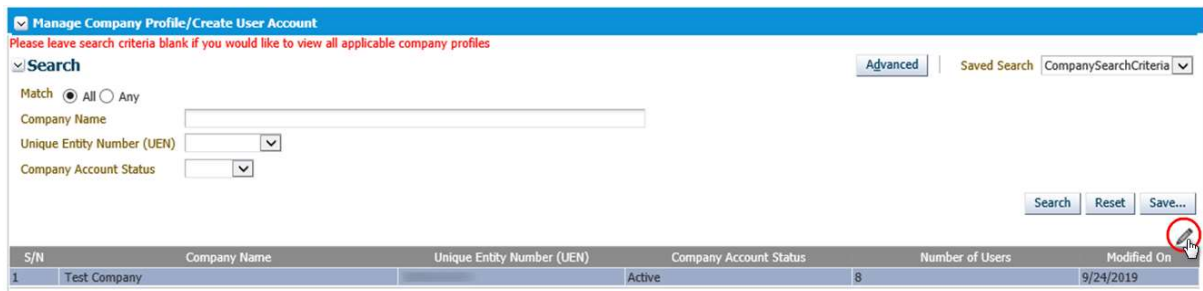
Functions: Manage company profile and company users' level of access to the OSCAR system.

2. OSCAR User

Functions: Perform FSCA report submission to the authority and act as the contact point with regards to the submitted FSCA case.


1.1.4. Account Creation

1. Click on the 'Identity Management' module from the Menu bar.
2. In the sidebar, click on the *Manage Company Profile/Create User Account* link.
3. In the search page, you may leave the search criteria empty and click on the *Search* button to display all company profiles tagged to the Corppass ID user.
4. Select the Company Profile to amend and click on the  button.



S/N	Company Name	Unique Entity Number (UEN)	Company Account Status	Number of Users	Modified On
1	Test Company		Active	8	9/24/2019

FIGURE 2. COMPANY PROFILE SEARCH

5. In the User Account section, click on the  button.
6. In the Account section, select the account type – External User (Corppass) and enter the NRIC/FIN number of the user in the login ID field.

Note: NRIC/FIN is for verification purposes. The user will use Singpass to access OSCAR.

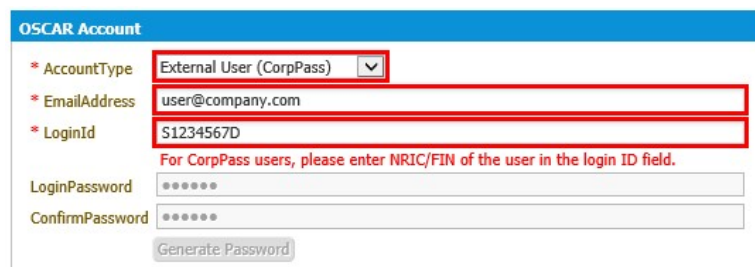



FIGURE 3. OSCAR ACCOUNT INFORMATION

7. In the Business Roles section, click on the  button and select the appropriate company module roles to be assigned to the user.

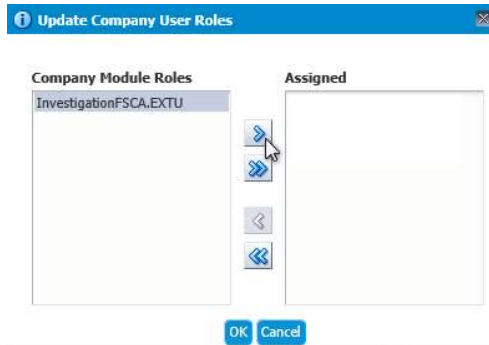


FIGURE 4. COMPANY USER ROLES

8. Complete the Personal Information section with the Name and Contact Number of the user

9. In the Company Roles section, select the appropriate role(s) to be assigned to the user. Refer to section 1.1.2. above for the functions for each user role.

10. Ensure that the Login status is unlocked and Account status is Active.



FIGURE 5. LOGIN AND ACCOUNT STATUS

11. Verify the user information and click on *Save and Close* to exit or *Save and Create Another* to create more user accounts.

1.2. OSCAR Workspace

The OSCAR Workspace displays the following sections: (1) Header and Menu, (2) Applications, (3) Task List, and (4) Work List View.

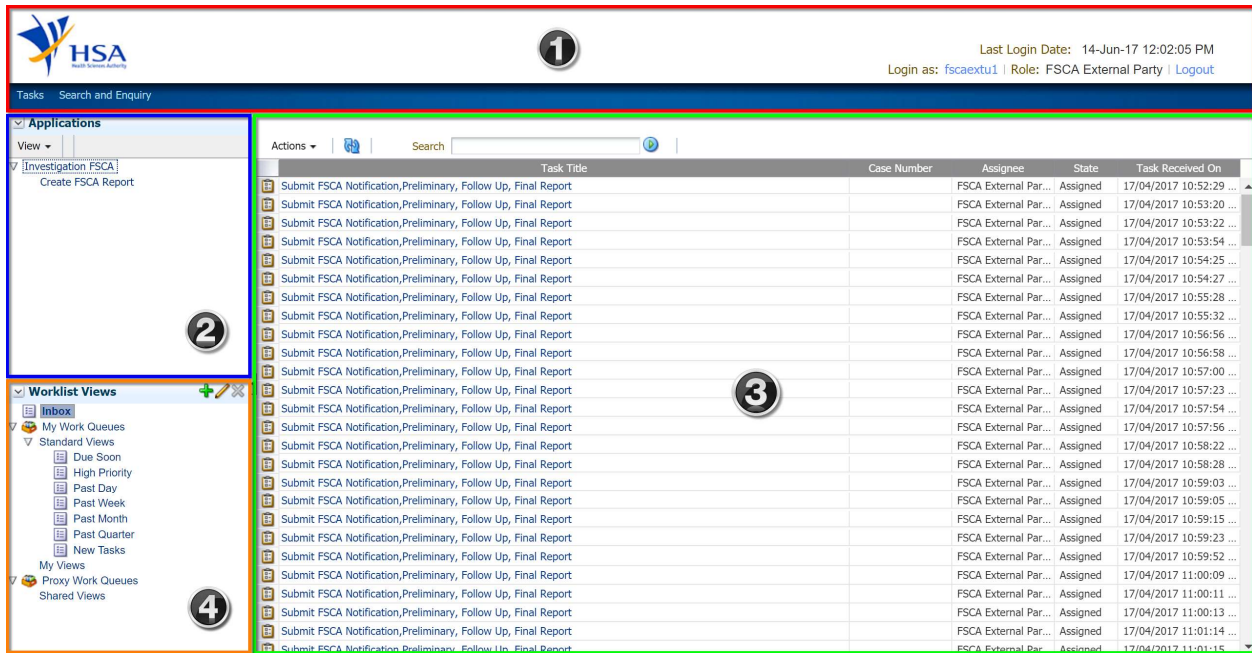


FIGURE 6. OSCAR WORKSPACE

1.2.1. Header and Menu

The Header section (1) displays the user name, and the last login date and time of the current user. The horizontal navigation Menu bar allows the user to navigate the *Tasks* and *Search and Enquiry* functions.

1.2.2. Applications Sidebar

The Applications sidebar (2) is located at the upper-left side of the Workspace. It contains the links to the different functionalities within module (i.e. Create new FSCA Report, or perform a Search and Enquiry).

1.2.3. Task List

The Task List section (3) displays all pending tasks which require the user’s actions. Please refer to the table below for the possible task titles and the corresponding scenario.

Task Title	Scenario
Draft FSCA Notification, Preliminary, Follow Up, Final Report	FSCA Report which was saved by the user and has not been submitted to MDB.
New FSCA Notification, Preliminary, Follow Up, Final Report	FSCA Report which was created but not saved.
Reply to RFA – “Case Number”	Input Request sent by MDB by the specified case, pending company’s response.

1.2.4. Worklist View

The Worklist View section (4) lists down the default and custom views which allows the user to filter the tasks which they wish to be displayed in the Task List section. Users can customize their own views using this function.

Note: To create custom Worklist Views, refer to [section 2.4 Creation of Custom Worklist Views](#).

2 USING THE SYSTEM

2.1. Submission of an FSCA Case

2.1.1. Create FSCA Report

1. Click on “Create FSCA report” link at the Applications sidebar

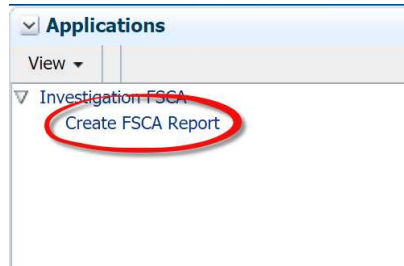


FIGURE 7. APPLICATIONS SIDEBAR

2. Select *New Case* if a new FSCA is to be submitted or *Existing Case* if a follow-up/final report is to be submitted for an existing case. The FSCA Reference Number has to be provided if the user wishes to submit a Follow-Up/Final Report for an ongoing case.

 A screenshot of a pop-up form titled 'Create an FSCA Report'. The form has a blue header. Below the header, there are two radio buttons: 'New Case' and 'Existing Case'. The 'Existing Case' radio button is selected and highlighted with a red box. Below the radio buttons, there is a text input field labeled '* FSCA Ref No:' containing the value '2017-FSCA-000001'. At the bottom of the form, there are two buttons: 'OK' and 'Cancel'.


FIGURE 8. CREATE FSCA REPORT POP-UP

3. (a) For *New Cases*, users will be required to declare if the affected devices have been manufactured or supplied in Singapore. Click on *Yes* or *No* accordingly. If *Yes*, the MDRR1 form will be displayed; If *No*, the MDRR3 form will be displayed.

 A screenshot of a pop-up form titled 'Create Report'. The form has a blue header. Below the header, there is a question: 'Have the medical devices affected by the FSCA been manufactured or supplied in Singapore?'. Below the question, there are two buttons: 'Yes' and 'No'.

FIGURE 9. POP-UP TO DETERMINE MDRR1 OR MDRR3 FORM

Before the FSCA form is displayed, a page which lists the instructions on how to properly fill in the form is shown. Please take time to read each instruction for your compliance.

(b) For *Existing Case*, click on  button at the “Reports” section within the form then select the type of report to be added and click OK.

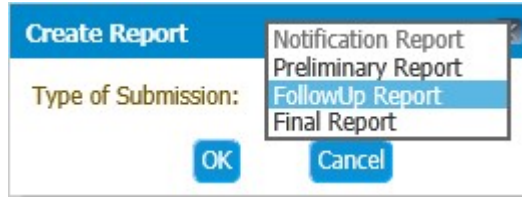


FIGURE 10. POP-UP FOR ADDITION OF REPORT

2.1.2. Filling in the FSCA Form

The fields marked with a red asterisk (*) are mandatory.

Reports

The Reports section contains the list of reports submitted for the particular FSCA case.



FIGURE 11. REPORTS SECTION

Case Information

The Case Information section contains basic details of the FSCA case.

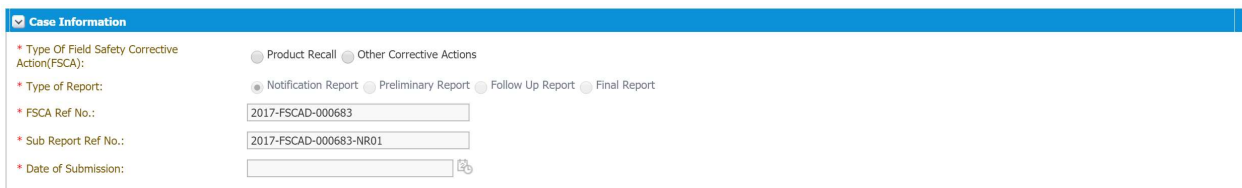


FIGURE 12. CASE INFORMATION SECTION

Company Particulars

The Company Particulars section contains the details of the Company involved in the FSCA case.

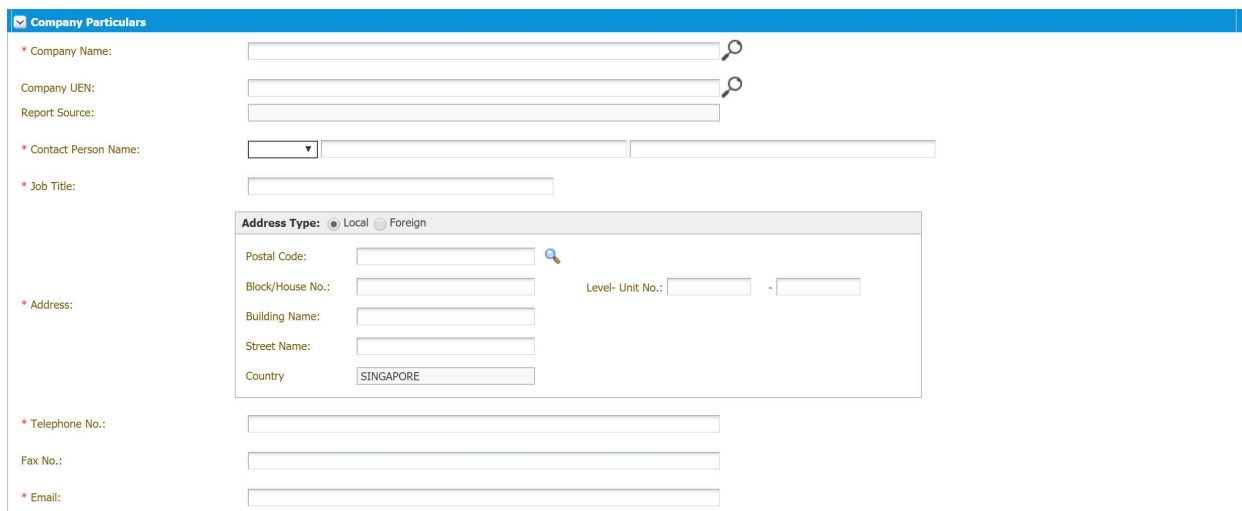


FIGURE 13. COMPANY PARTICULARS SECTION

Device Details

The Device Details table contains the information of the device(s) involved in the FSCA case.

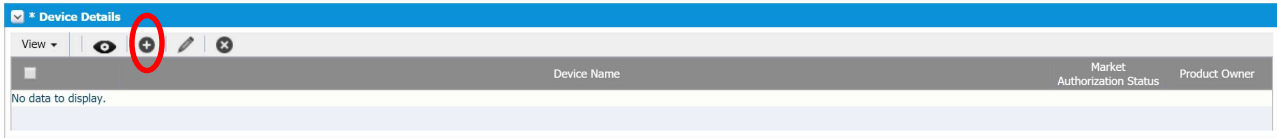


FIGURE 14. DEVICE DETAILS SECTION

Click on the button to add an entry for each device affected by the FSCA. Please provide all mandatory details for the device that is affected by the FSCA.

If the affected device is registered on SMDR, users may select the affected listing numbers from the (search) function at the SMDR Listing No. field.

Device Details

* Status of Marketing Authorization:

* SMDR Listing No.:

* Device Name:

* Device intended use:

MD Risk Class:

Model No.:

Catalogue No.:

Serial No.:

Lot/Batch No.:

Accessories / Associated Devices affected (if any):

* Product Owner:

Address Type: Local Foreign

Postal Code:

Block/House No.: Level- Unit No.: -

Building Name:

Street Name:

Country:

* Product Owner Address:

Upload Product Status:

Alternatively, you may use this file as a template Product Status Upload File.xlsx

Manufacturer, Wholesaler, Importer, and Registrant Information

View

Company Name	Type of Company	Contact Person Name	Job Title	Telephone No.	Fax No.	Email
No data to display.						

FIGURE 15. ADD DEVICE DETAILS POP-UP

FSCA Information

The FSCA Information section contains the details of the FSCA. Depending on the report, the fields in the MDRR1, MDRR2, or MDDR3 report may differ. Users are to complete the report and upload relevant FSCA documents within this form.

FSCA Information

* FSCA strategy:

* Have the medical devices affected by the FSCA been manufactured or supplied in Singapore? Yes No

* Is the FSCA implemented in Singapore? Yes No

* Did the FSCA arise due to an adverse event? Yes No

Evaluation of the risk associated with affected device(Health Hazard Evaluation Report):

Health Hazard Evaluation(HHE) Report: Choose File No file chosen ✕

Reason for the FSCA:

A copy Of FSCA communication: Choose File No file chosen ✕

Affected device details(e.g device identifiers,lot/batch numbers) listed in the FSCA Communication: Contains affected device details for the global market
 Contains affected device details for Singapore only

Dear Healthcare Professional Letter: Choose File No file chosen ✕

* Has the FSCA communication been sent to all consignees? Yes No

Countries to which has this FSCA has been reported (if any):

* Date of commencement of FSCA by product owner: 🗑

* Date of commencement of FSCA in Singapore: 🗑

* Proposed date of completion of FSCA in Singapore: 🗑

Summary of Root Cause Analysis:

Summary of Corrective and Preventative Action (CAPA):

Summary of CAPA Effectiveness:

FIGURE 16. FSCA INFORMATION SECTION

Change Notification Details

If a change notification is to be submitted for the affected devices in the FSCA, the company is required to clarify the type of change which is applicable, with respect to the GN-21 Guidance on Change Notification for Registered Medical Devices.

For software changes, the company is also required to identify changes implemented in the upgraded software which are not related to the FSCA.

Change Notification Details(if applicable)

Type of change with reference to GN-21 (e.g software change, design change, labelling change):

For software-related changes have any features not related to this FSCA been incorporated?(If Yes, please provide further details in the Software Details table below): Yes No

Software Details:

Software Details	Current Approved	Proposed
Name of Software	<input type="text"/>	<input type="text"/>
Version Number	<input type="text"/>	<input type="text"/>
Intended use of the software	<input type="text"/>	<input type="text"/>
Description of the differences between current and proposed software.	<input type="text"/>	<input type="text"/>

FIGURE 17. CHANGE NOTIFICATION DETAILS

Other Information

Additional information, comments, and other supporting documents may be provided in the “Other Information” section.

Other Information

Other Information:

Other Attachments: No file chosen

FscA Report RefNo	Document Name	Document Type	Created Time
No data to display.			

FIGURE 18. OTHER INFORMATION SECTION

Note: The following document types are not permitted in OSCAR - .doc ; .xls ; .ppt ; .msi ; .exe.
 Note: The file size limit is 20Mb.

Declaration and Submission of Report

A declaration section at the end of the page is required to be completed before submission of the report.

Declaration

The changes indicated in the Software Details table above are not related to any FSCA and the medical device with the additional software features conform(s) to the Essential Principles for Safety and Performance as specified in the Health Products (Medical Devices).

I attest that the information submitted is true and accurate, and that I am authorized to submit this form on behalf of the company.

Date of this notification:

FIGURE 19. DECLARATION SECTION

Once all the necessary information has been completed, please click on the *Submit* button and a FSCA Reference Number will be issued for your reference. Please keep note of this reference number for future submission of Follow-Up/Final Reports or future correspondences.

2.2. Replying to an RFA

A Request for Action (RFA) task will be sent to the company if more information regarding the FSCA is required for review. The RFA will contain input requests which require the company's response.

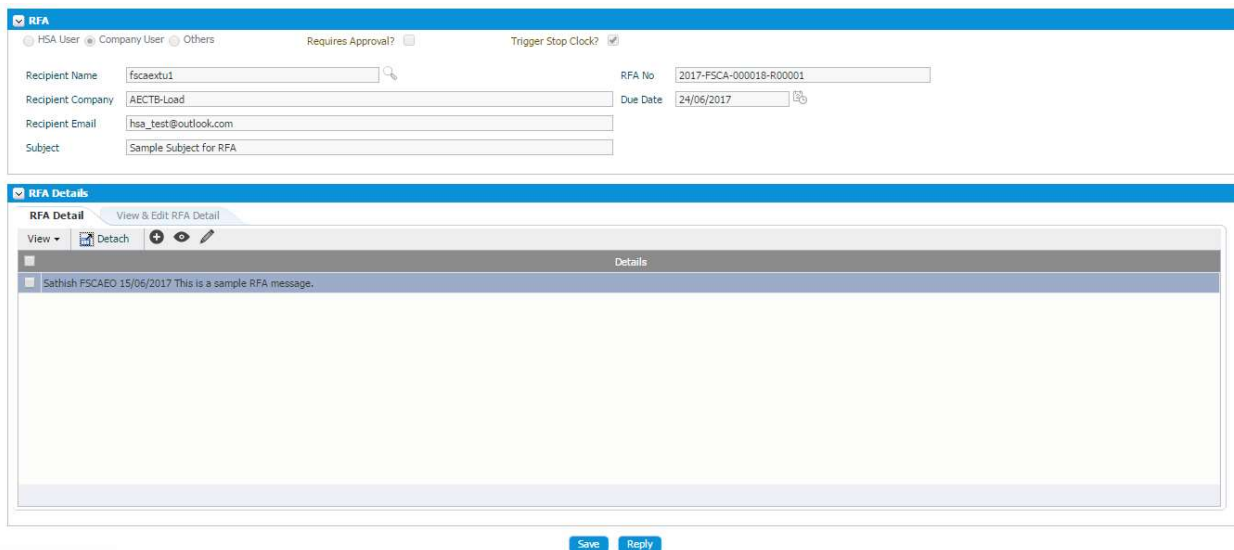
The task will appear as “*Reply to RFA - <FSCA Reference No.>*” in task list. In addition, an auto-generated email will also be sent to the email address of the contact person provided in the FSCA report. Please do not reply to the auto-generated email as we will not receive this response. All responses to the input requests should be submitted via the RFA task in OSCAR.



Task Title	Case Number	Assignee	State	Task Received On
Reply to RFA - 2017-FSCA-000018		Sathish FSCAEP	Assigned	15/06/2017 06:16:16 ...
Submit FSCA Notification,Preliminary, Follow Up, Final Report		Sathish FSCAEP	Assigned	13/06/2017 05:11:56 ...
Submit FSCA Notification,Preliminary, Follow Up, Final Report		Sathish FSCAEP	Assigned	13/06/2017 04:53:44 ...
Submit FSCA Notification,Preliminary, Follow Up, Final Report		Sathish FSCAEP	Assigned	08/06/2017 01:14:22 ...

FIGURE 20. AN RFA TASK IN THE TASK LIST

The RFA screen consists of the basic information such as the Due Date for response, as well as the details of the input requests.



RFA

HSA User Company User Others Requires Approval? Trigger Stop Clock?

Recipient Name: RFA No:

Recipient Company: Due Date:

Recipient Email:

Subject:

RFA Details

RFA Detail View & Edit RFA Detail

View

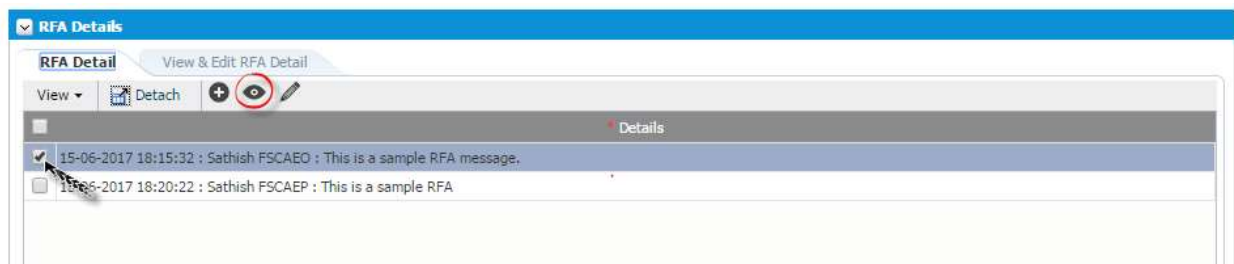
Details

Sathish FSCAEO 15/06/2017 This is a sample RFA message.

[Empty message]

FIGURE 21. RFA SCREEN

To view the full message of the RFA that was sent, navigate to the RFA Details section, and tick/check the message, and click on the view (👁) button.



RFA Details

RFA Detail View & Edit RFA Detail

View

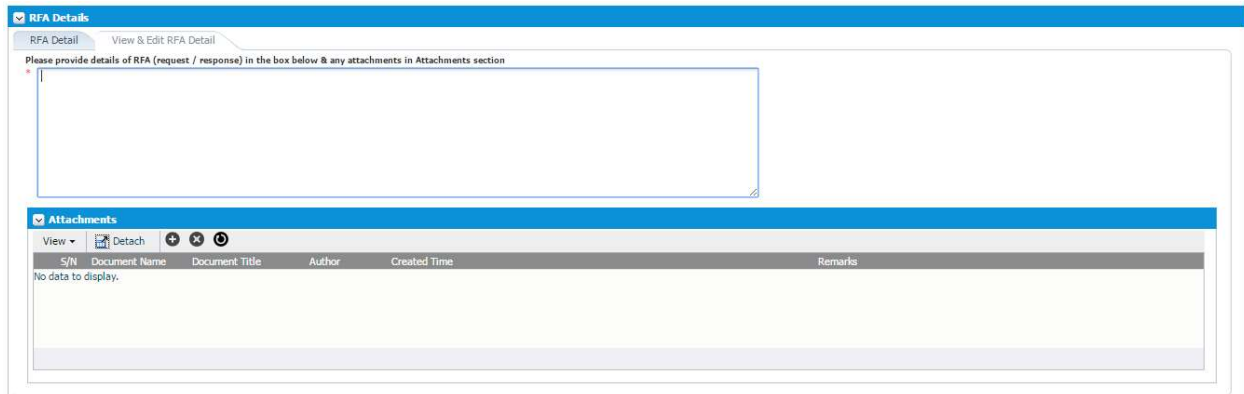
Details

15-06-2017 18:15:32 : Sathish FSCAEO : This is a sample RFA message.

15-06-2017 18:20:22 : Sathish FSCAEP : This is a sample RFA

FIGURE 22. VIEWING AN RFA MESSAGE

To reply to the RFA, click on the add (+) button, and enter the response. To attach a document, navigate to the Attachments section, and click on the add (+) button to add a file.



The screenshot displays the 'RFA Details' interface. At the top, there is a blue header bar with 'RFA Details' and a 'View & Edit RFA Detail' button. Below the header, a text area is provided for entering details, with a prompt: 'Please provide details of RFA (request / response) in the box below & any attachments in Attachments section'. Below the text area is an 'Attachments' section with a blue header bar containing 'View', 'Detach', and two buttons with plus and minus signs. Underneath is a table with columns: 'S/N', 'Document Name', 'Document Title', 'Author', 'Created Time', and 'Remarks'. The table currently shows 'No data to display.'

FIGURE 23. ADDING AN RFA MESSAGE

Once all information has been provided, click on the “Reply” button to submit the response.

2.3. FSCA Case Search for Companies

The FSCA Case Search for Companies page is a search and enquiry function where all the FSCA cases submitted by the company can be searched. Only cases submitted by the current user will be accessible.

To access the FSCA Case Search page, click on the ‘Search and Enquiry’ from the Menu bar. Under the Applications sidebar, click on the *FSCA Case Search* link.



FIGURE 24. FSCA CASE SEARCH FOR COMPANIES LINK

Upon clicking the link, the page will be redirected to the FSCA Case Search screen. It consists of two main portions, the search criteria panel at the top displays criteria of the search, while the search results panel at the bottom displays the results of the search.

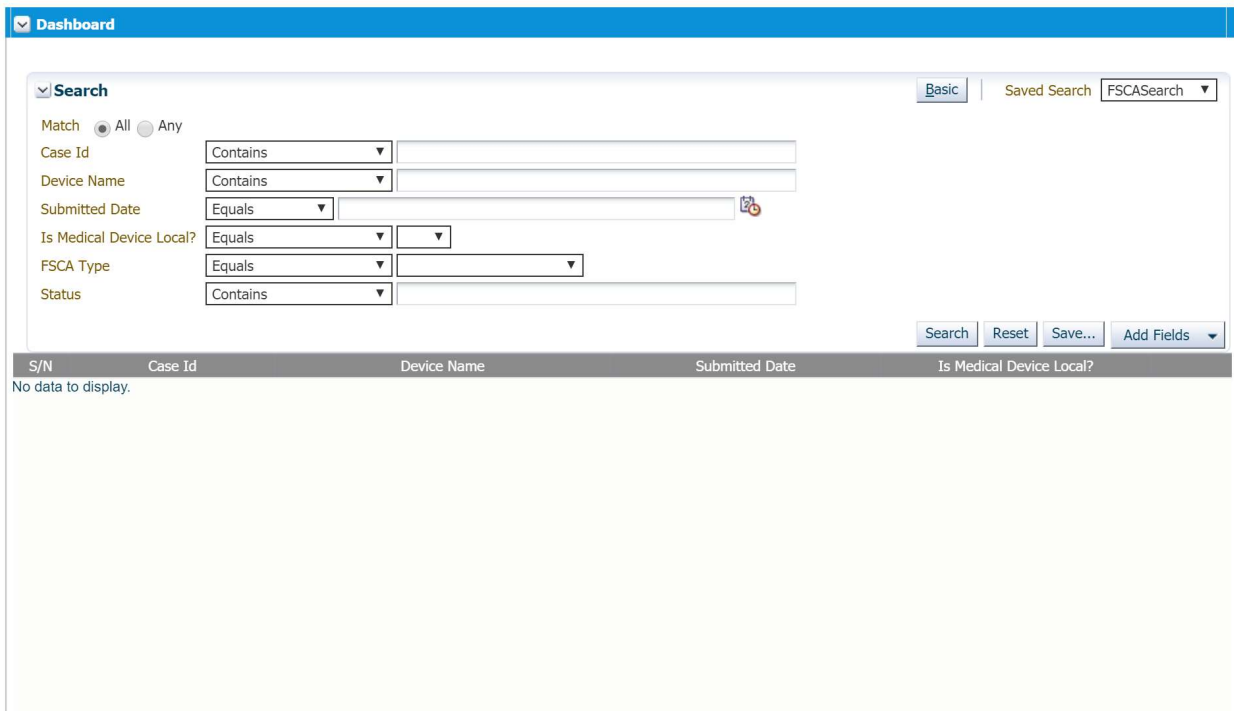


FIGURE 25. FSCA CASE SEARCH SCREEN

2.3.1. Performing a Search

To perform a search, fill in the respective search field, and click on the Search button.

The Search Criteria section has two forms: *Basic Search* and *Advanced Search*. To toggle between the two forms, click on the button beside the Saved Search dropdown. The Advanced Search option allows users to customize the search parameters as well as add in operators for a tailored search.

FIGURE 26. ADVANCED SEARCH

2.3.2. Creating a Saved Search

This feature allows the user to save a particular set of search criteria and the corresponding search results.

To create a Saved Search, customize the search criteria and click on Search to generate the results. Then, click the “Save” button.

FIGURE 27. SAVING A SEARCH

Upon clicking “Save”, the user will be required to enter a name for the customized search.

FIGURE 28. CREATING A SAVED SEARCH

After the Saved Search is saved, it will be listed in the Saved Search dropdown menu where users may access the customized search parameters without the need to re-do the customization.

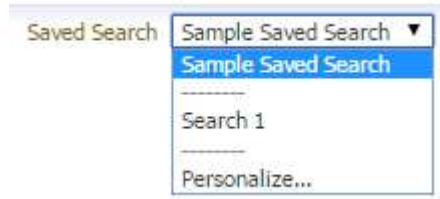


FIGURE 29. SAVED SEARCH DROPDOWN

2.3.3. Deleting a Saved Search

To delete a saved search, select “*Personalize...*” under the Saved Search dropdown list. The Personalize Saved Searches pop-up will subsequently be displayed.



FIGURE 30. SAVED SEARCH DROPDOWN

At the pop-up window, select the saved search you would like to delete from the drop down list, and click the Delete button.

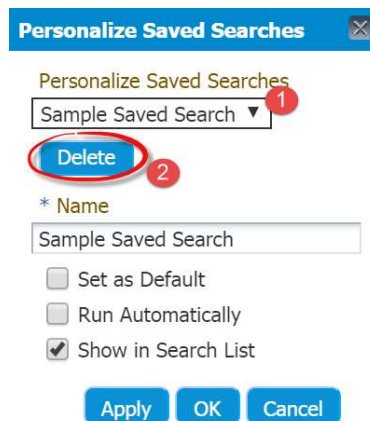


FIGURE 31. PERSONALIZE SAVED SEARCH POPUP

Once the Delete button is clicked, a warning pop-up will display to confirm the deletion. Click Yes to proceed with the deletion; click No to cancel it.

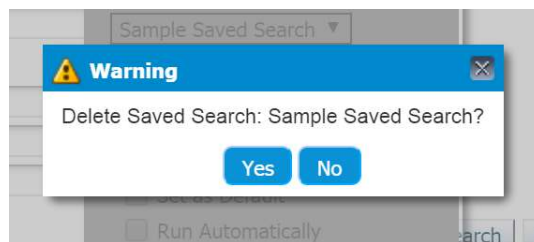



FIGURE 32. DELETE SAVED SEARCH POPUP

2.4. Custom Worklist Views

Custom Worklist Views allows filtering of tasks on the task list according your own criteria.

2.4.1. Creation of a Custom Worklist View

To create a custom worklist view, navigate to the Worklist Views section located at the bottom-left sidebar of the Workspace. If the section is collapsed, click on the  (two arrows pointing downwards) icon to show it.

Click on the  button. The “Create User View” pop-up shall be displayed.

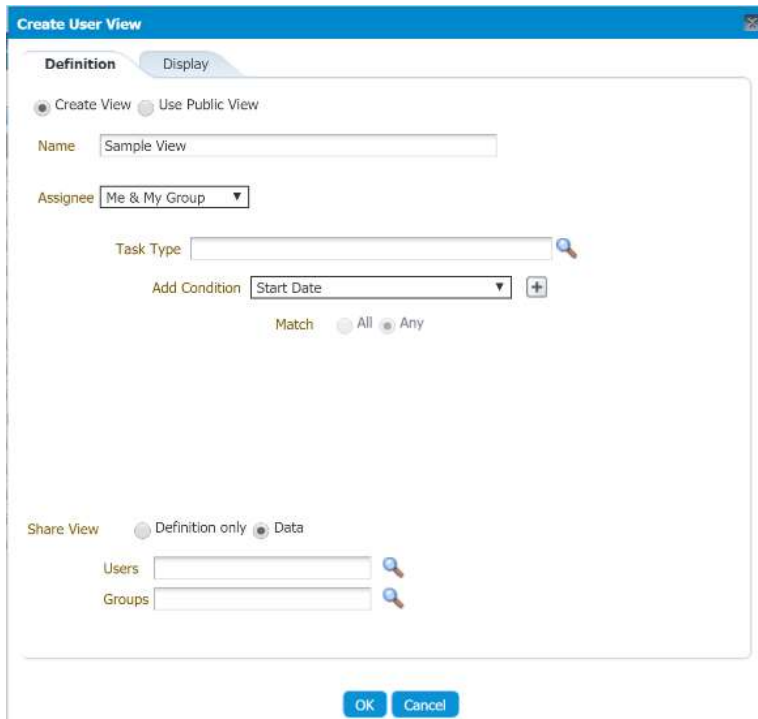


FIGURE 33. CREATE USER VIEW POPUP

2.4.2. Worklist Views Criteria for Users

Below are some sample criteria you can create for your own worklist views:

1. Filtering “Reply to RFA” Tasks

The screenshot shows the 'Create User View' dialog box with the following configuration:

- Definition** tab is selected.
- Create View Use Public View
- Name: "Reply to RFA" Tasks
- Assignee: Me
- Task Type: (empty)
- Add Condition: Title
- Match: All Any
- Title: contains Reply to RFA
- Share View: Definition only Data
- Users: (empty)
- Groups: (empty)
- Buttons: OK, Cancel

FIGURE 34. “REPLY TO RFA” TASKS CUSTOM WORKLIST VIEW

2. Filtering “Draft” tasks

The screenshot shows the 'Create User View' dialog box with the following configuration:

- Definition** tab is selected.
- Create View Use Public View
- Name: Draft Tasks
- Assignee: Me
- Task Type: (empty)
- Add Condition: Title
- Match: All Any
- Title: contains New FSCA
- Share View: Definition only Data
- Users: (empty)
- Groups: (empty)
- Buttons: OK, Cancel

FIGURE 35. DRAFT TASKS CUSTOM WORKLIST VIEW

2.4.3. Deletion of Unused Tasks and Draft Cases

An unused task and FSCA cases still in “Draft” status may be deleted.

Unused Tasks. An unused task refers to a task which is empty and not linked to a case. The task title of an unused task is “*New FSCA Notification, Preliminary, Follow Up, Final Report*”, and no case number is assigned to it.

To delete an unused task, user will have to first create a dummy case and click on “Delete” button within the FSCA form when it is displayed.

“Draft” FSCA Cases. On the other hand, an FSCA case in “Draft” status refers to a case which have been saved as draft through clicking the “Save” button. The task title of a draft case is “*Draft FSCA Notification, Preliminary, Follow Up, Final Report*”, and a temporary case number is assigned to it.

To delete an FSCA case in “Draft” status, click on the task and click on the “Delete” button on the FSCA form page.

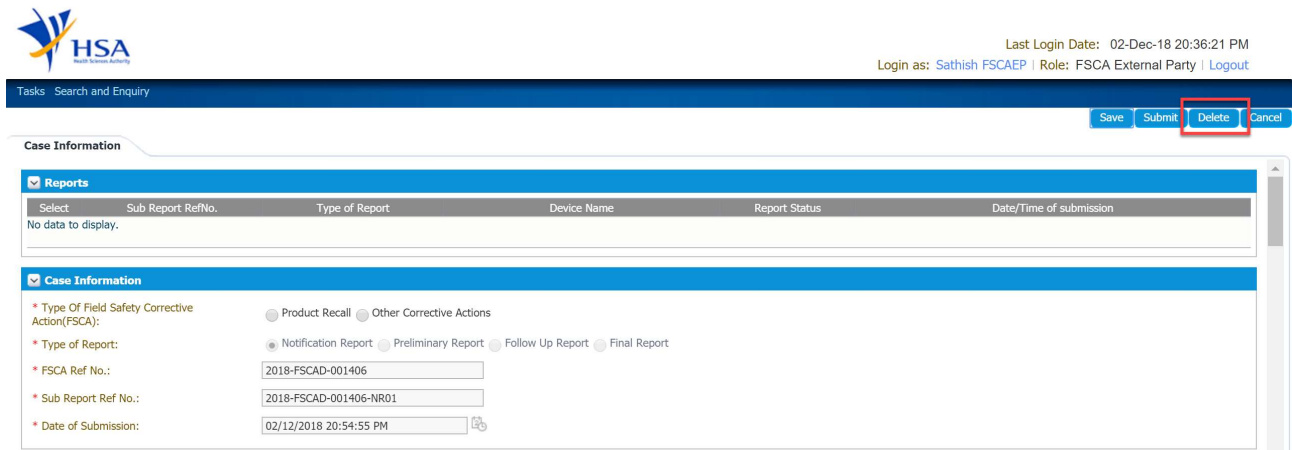


FIGURE 36. FSCA FORM

A confirmation pop-up will be displayed to confirm the deletion. Click on the “Yes” button to proceed.

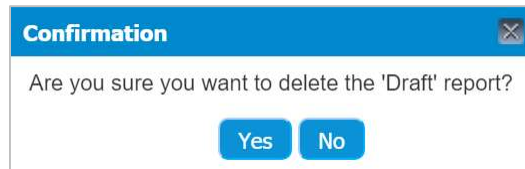


FIGURE 37. DELETION CONFIRMATION POPUP

Once deleted, the task will be removed from your task list.

END OF DOCUMENT