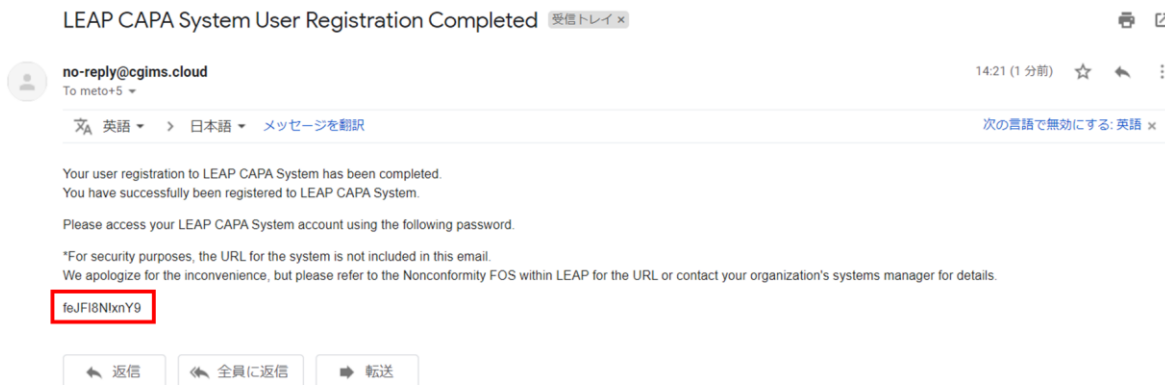


CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

Logging into the system and changing your password (all users)

- 1) When you are registered as a user on CAPAct, an automatic email will be sent with a temporary password. (See screen below)



- 2) Note that the URL to CAPAct is not detailed within this email; therefore, you will need to open the app using the URL supplied to you by CGI. Once the app is open using a web browser, enter your email address and temporary password to login.
- 3) Read through the End-User License Agreement (EULA) and click “Agree”.
- 4) Now that you are logged in, click on “Account” in the left menu. General details will be displayed on this screen. Insert your temporary password into “Current password” and enter in your “New password” and click “Save”. Once your password is successfully changed, a message in green stating “Changes have been successfully reflected” will show up on the top of the screen. Note that you can also change other settings including preferred languages (English or Japanese) and default ticket view (Card or List) on this screen.

The screenshot displays the CAPAct web application interface. On the left is a vertical navigation menu with the following items: 'My Tickets', 'All Tickets', 'Contents', 'Users', 'Logs', 'Account', and a green button labeled '+ Create Ticket'. The main content area shows a form for creating a new ticket. The form includes the following fields and controls:

- Name:** A text input field containing the value 'Ayame'.
- Email:** A text input field containing the value 'meto+2@cgikk.com'.
- Language:** A dropdown menu with 'en' selected.
- Default view:** A dropdown menu with 'Card' selected.
- Current password:** A text input field with the placeholder text 'Enter only when changing password'.
- New password:** A text input field with the placeholder text 'Enter only when changing password'.
- Confirmation:** A text input field with the placeholder text 'Please enter the password above for confirmation'.
- Save:** A button located at the bottom of the form.

Adding/Disabling users (Master Users only)

- 1) To add other users to the organization, click on “User” in the left menu.
- 2) Click on “New” on the right corner of the screen (as indicated in red on Fig1 below).
- 3) A pop-up screen (Fig2) will show up. Enter in all relevant fields including the name of the user and their respective email. Click “Save”. Note that organization users can only add general users. Master users can only be added to an organization by CGI.
- 4) An email will automatically be sent to the registered user’s email address with a temporary password.
- 5) To disable users, click on the Tool icon next to the user you wish to disable (as indicated in orange on Fig1 below).
- 6) A pop-up screen (Fig2) will show up. Click on the “Disable” button at the very bottom and click “Save”.

Fig1. User Screen

CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

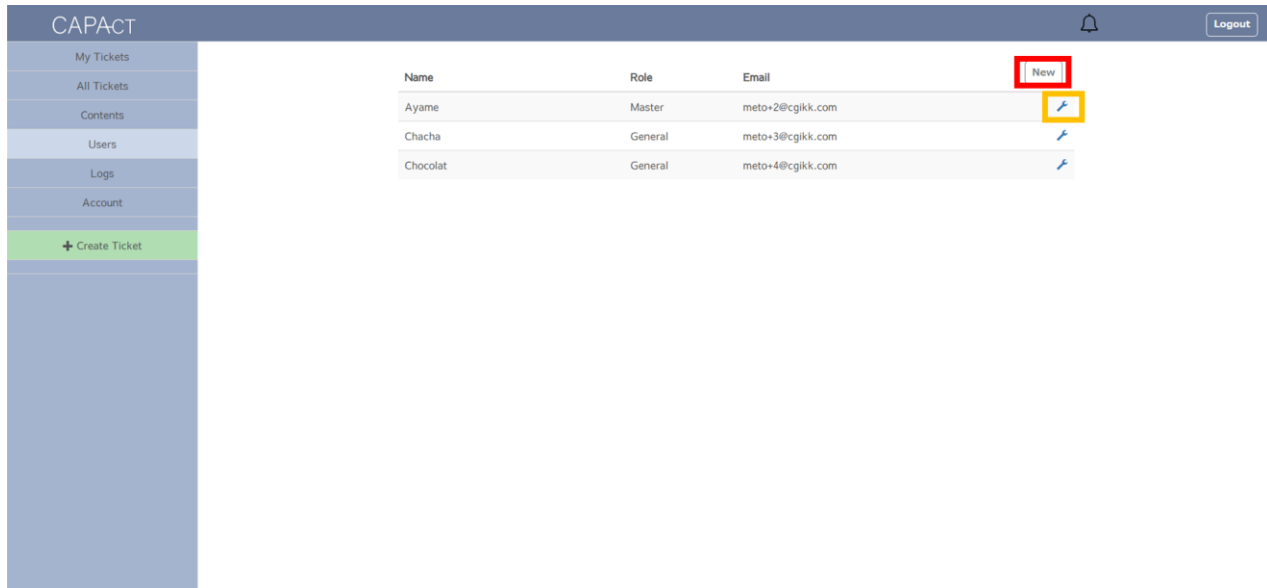


Fig2. Editing User Information Screen

New / Editing User

Name:

Role:

Language:

Email:

Default view:

Disable: ☐

Changing the content of pull-down menu (Master Users only)

- 1) To change the content of the predefined pull-down menu, click on “Contents” in the left menu.
- 2) To add a new content, simply type in your new content in the text box provided at the bottom of the screen (indicated in red) and click “Add”.

CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

- 3) To edit an existing content, click on the tool button next to the relevant content (indicated in orange) and make changes in the pop-up screen and click “Save”. Note that editing an existing content for which tickets are already assigned will lead to the edits being reflected in all tickets (including the ones that have been completed).
- 4) To delete an existing content, simply click on the trash box next to the relevant content (indicated in green) and click “Delete”. Note that deleting content cannot be undone. Also, if the content is already assigned to a ticket, it cannot be deleted.
- 5) To change the order of how the content displays in the pull-down menu, drag and drop the content as needed to display the correct order and click “Save Order” (indicated in blue).
- 6) All changes to the content can be viewed in the log at the bottom of the screen.

The screenshot displays the CAPAct interface with a sidebar on the left containing navigation links: My Tickets, All Tickets, Contents, Users, Logs, Account, and a green button for '+ Create Ticket'. The main area shows two side-by-side tables. The left table, titled 'Observed/Affected location', lists 14 items with associated 'Save Order' and edit/delete icons. The right table, titled 'General Category', lists 12 items with similar icons. Both tables have an 'Add' button at the bottom with a text input field. The 'Save Order' buttons are highlighted with blue boxes, and the edit/delete icons are highlighted with orange and green boxes respectively.

Order	Observed/Affected location	Save Order	Edit	Delete
1	Entire Laboratory (GEN/DRA/COM)			
2	Anatomic Pathology (ANP)			
3	Clinical Biochemical Genetics (CBG)			
4	Chemistry (CHM)			
5	Cytogenetics (CYG)			
6	Cytopathology (CYP)			
7	Flow Cytometry (FLO)			
8	Hematology (HEM)			
9	Histocompatibility (HSC)			
10	Immunology (IMM)			
11	Microbiology (MIC)			
12	Molecular Pathology (MOL)			
13	Transfusion Medicine (TRM)			
14	Urinalysis (URN)			

Order	General Category	Save Order	Edit	Delete
1	Pre-analytical events			
2	Analytical events			
3	Post-analytical events			
4	PT/alternative assessment events			
5	Accidents/incidents			
6	Complaints			
7	System issues			
8	Audits			
9	Personnel issues			
10	Facility issues			
11	QM issues			
12	Other			

Viewing tickets (all users)

- 1) There are two dashboards for viewing tickets. The “My Tickets” dashboard is a dashboard summarizing tickets you have created. The “All Tickets” dashboard is a dashboard summarizing all tickets created within your organization.
- 2) Both dashboards display a pie chart on the top categorizing tickets into “Ongoing” (i.e., tickets that have not been completed and are still within the final due date for Evaluation of Efficacy; indicated

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

in blue), “Late” (i.e., tickets that have not been completed and are past the defined due date; indicated in pink), “Completed Late” (i.e., tickets that were completed but were completed past the defined due date; indicated in yellow), and “Completed” (i.e., tickets that were completed on time; indicated in green). Note that this pie chart changes as you filter or search for specific tickets. For example, if you filter location and select “Entire laboratory”, only tickets with this content selected for Observed/affected location will display both in the ticket list and in the pie chart.

- 3) Below the pie chart (identified in red on Fig1) is where you can filter and search for specific tickets. For keyword searches, commas must be entered between two words if you would like to search for tickets including words A and/or B (e.g., Unacceptable, PT). If you do not type in a comma, the search will consider it one word and will search for tickets that include the word AB (e.g., Unacceptable PT). Note that the general keyword search does a search in all text fields (i.e., title, identify the problem, investigation detail (RCA), corrective and/or preventative action, and evaluating efficacy of action).
- 4) Advanced searches can be performed by clicking on the accordion symbol (indicated in orange on Fig1). Here, you can search for tickets that are assigned urgent status or that have been archived; search for tickets that were created within a certain timeframe; or do a narrowed keyword search so the system only searches for the keyword in your indicated text field.
- 5) While all tickets are displayed based on your default ticket view, you can change this view by selecting the preferred view in the View section (indicated in green on Fig1). While both views will contain the same information, a card view is preferable if you want to see tickets in a more isolated view; a list view is preferable if you want to glance at multiple tickets at once.
- 6) Status of the ticket is determined by the final due date (i.e., the due date you set for the last step: Evaluating Efficacy of Action). However, you can see the stage of the card and the status of the stage in the ticket view. Note that when a stage is due in 7 days, the due date indicated next to the stage changes to an orange color. If the stage is past its due date, the number of days late is indicated in pink. (See Fig2 for list view and Fig3 for card view).
- 7) To view details of a ticket, simply click on the relevant ticket in the list or card view.

Fig1. Top part of ticket dashboard

CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

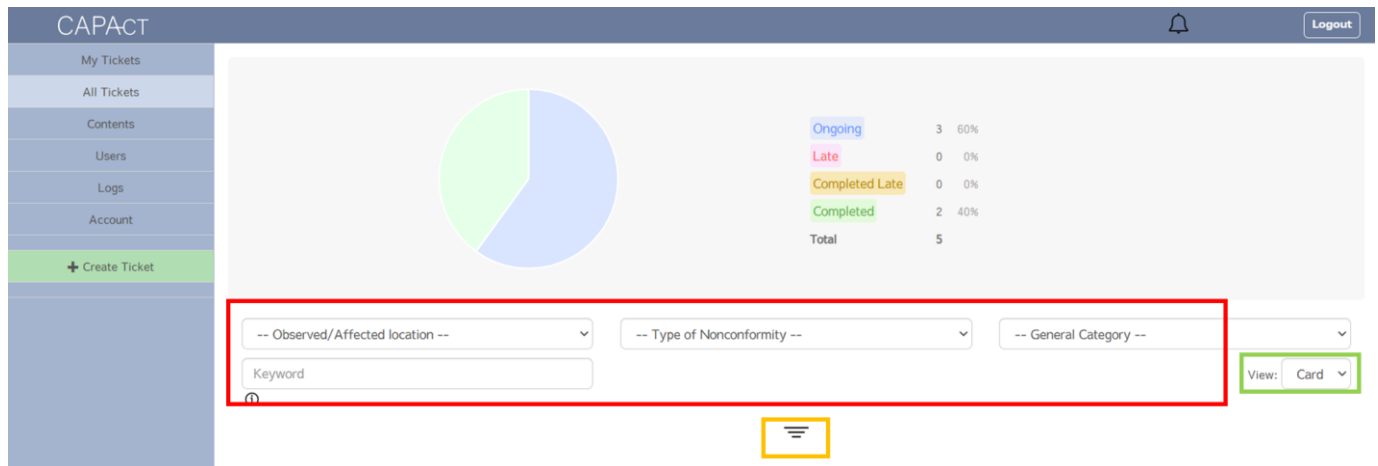


Fig2. List view of tickets

CAPAct					
<div>My Tickets</div> <div>All Tickets</div> <div>Contents</div> <div>Users</div> <div>Logs</div> <div>Account</div> <div>+ Create Ticket</div>					
Report #	Stage	Observed/Affected location	General Category		
Initial Report Date/Time	Report by	Type of Nonconformity	Due Date		
Title			Approved Date	Approver	
2021-0006	RCA Due in 2 Day(s)	Entire Laboratory (GEN/DRA/COM)	Pre-analytical events		
2021-02-05	Chacha	Actual	TBD		
Trying out new features.			Ongoing		
2021-0004	Evaluating Efficacy of Action Due in 29 Day(s)	Entire Laboratory (GEN/DRA/COM)	Personnel issues		
2021-02-02	Mimi	Potential	2021-03-30		
Employee training			Ongoing		
2021-0001	RCA Delayed 21 Day(s)	Anatomic Pathology (ANP)	Pre-analytical events		
2021-02-02	Ayame	Actual	2021-04-30		
ANP.10038 Client A tissue quality			Ongoing		
2021-0002	RCA	Hematology (HEM)	Complaints	Ayame	
2021-02-02	Chacha	Actual Urgent ⚠	2021-02-05		
GEN.20325 STAT Test TAT Client A			2021-02-05 Completed		
2021-0003	RCA	Chemistry (CHM)	PT/alternative assessment events	Ayame	
2021-02-02	Chocolat	Actual	2021-02-02		
COM.01700 Unacceptable PT result for CM-14 CAP PT			2021-02-02 Completed		

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

Fig3. Card view of tickets

The screenshot shows the CAPAct user interface. On the left is a sidebar with the following menu items: CAPACT, My Tickets, All Tickets, Contents, Users, Logs, Account, and a green button labeled '+ Create Ticket'. The main content area displays three ticket cards. Each card has a title, a status indicator (Ongoing), a report number, a report date, a stage, a due date, an observed/affected location, a type of nonconformity, a general category, an approved date, and an approved by field.

Ticket Title	Status	Report #	Report Date	Stage	Due Date	Observed/Affected Location	Type of Nonconformity	General Category	Approved Date	Approved By
Trying out new features.	Ongoing	# 2021-0006	Chacha 2021-02-05	RCA	Due in 2 Day(s)	Entire Laboratory (GEN/DRA/COM)	Actual	Pre-analytical events		
Employee training	Ongoing	# 2021-0004	Mimi 2021-02-02	Evaluating Efficacy of Action	Due in 29 Day(s)	Entire Laboratory (GEN/DRA/COM)	Potential	Personnel issues		
ANP.10038 Client A tissue quality	Ongoing	# 2021-0001	Ayame 2021-02-02	RCA	Delayed 21 Day(s)	Anatomic Pathology (ANP)	Actual	Pre-analytical events		

Creating tickets (all users)

- 1) Tickets can be created by anyone who is a registered user in the organization by simply clicking on "Create Ticket" in the left menu.
- 2) In order to register a ticket, you must fill out the following and then save:
 - a. Observed/affected location
 - b. Type of nonconformity
 - c. General category
 - d. Title
 - e. Identify the Problem

NOTE: You can select Urgent and due dates for all stages at this point, but these are not mandatory fields.
- 3) Once you click save, the other parts of the ticket will be made available for use.

CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

Observed/Affected location: --Select-- ⓘ

Type of Nonconformity: --Select-- ⓘ

General Category: --Select-- ⓘ

Urgent: ☐

Title: Required Field

Identify the Problem: Required Field

Fill this section out and click save before proceeding with the rest of the ticket.

Save

Uploading files as evidence (all users)

- 1) Each stage has an attachment function, and relevant evidence should be uploaded as necessary. To see what files are already attached or to attach a new document, simply click on the paperclip mark underneath the relevant stage (indicated in red).
- 2) Any files that have already been uploaded will be displayed as a list form with the upload date and person indicated. Files that have been uploaded can be deleted by clicking on the trash icon (indicated in orange).
- 3) To select a new document to upload, click on Choose File, select the relevant document and click upload (indicated in green).

CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

Approving tickets (all users)

- 1) Once details of a ticket have been completed (all details up until Evaluating Efficacy of Action), the ticket is ready for approval. In order to approve a ticket (can approve any ticket if you are a Master User; can approve any ticket you did not create if you are a General User), click on the Approve button at the bottom of the Ticket Detail screen.
- 2) A pop-up screen shows up for approval. If only a single approver is necessary, the approver shall just click "Approve" (indicated in red). If multiple approvals are necessary, the approver shall click on the "Request for additional approval" (indicated in orange) before clicking "Approve". This process can be done as many times as needed.

Exporting tickets (all users)

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

- 1) Details of the ticket can be exported to an Excel format if necessary. Simply click on the “Excel output” button on the right side at the bottom of the ticket detail (indicated in red). Note that attached files will not be downloaded or reflected in the document, but the number of attachments in each stage are noted in the exported Excel report.

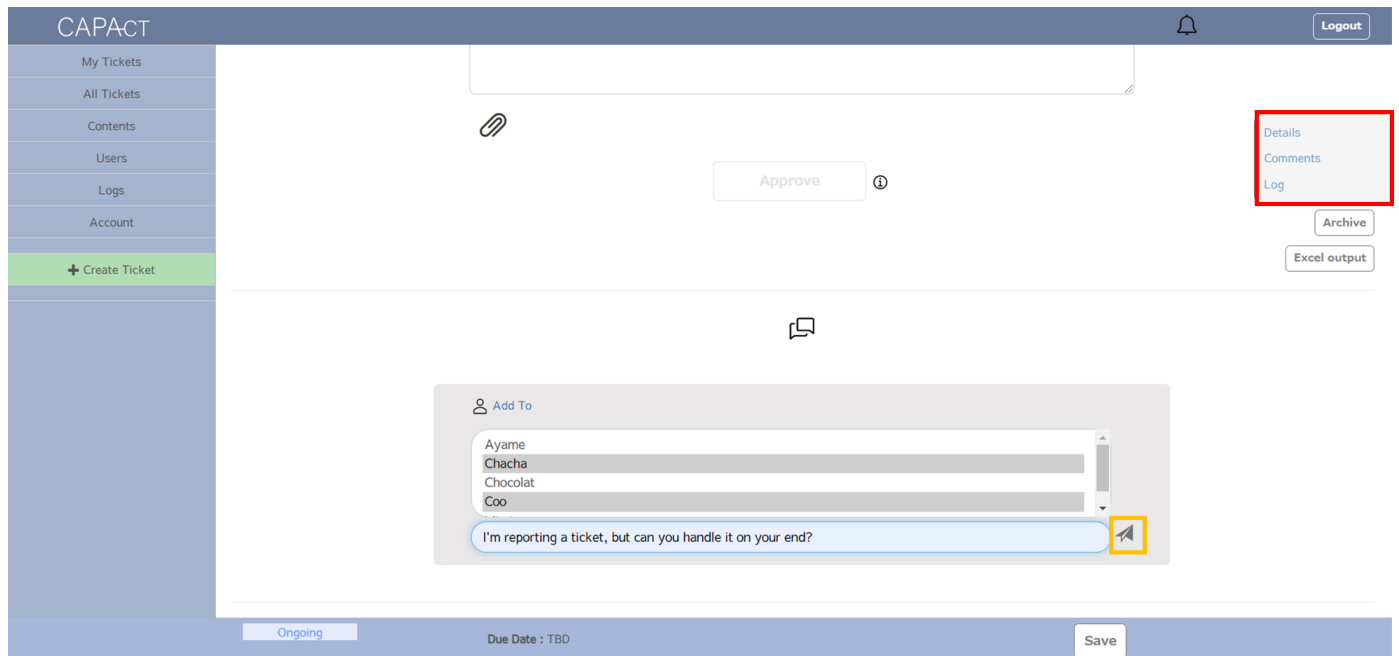
Making comments (all users)

- 1) Once the ticket has been created (see above), the Comments and Log section become available. Clicking on Comments on the right side of the screen takes you directly to the Comments section for this ticket (indicated in red on Fig1).
- 2) To direct a message to a different user in the organization, click the “Add To” button, and a list of all users within the organization will show up. Select the users you want to message. You can select multiple users by holding down the Ctrl button and selecting the relevant users. Write a message in the text field below the user selection, and then click the “Send” icon (indicated in orange on Fig1).
- 3) Users selected will receive notification that a message has been sent to them when they login to CAPAct as the bell sign on the right corner will be marked with the number of unread messages (indicated in red on Fig2). Clicking on the number will show a list of messages. To view the relevant card, simply click on View (indicated in orange on Fig2), which will take you to the comment section of the relevant ticket. Once you have read the message, the message will be marked with a check mark to indicate the message has been read (Fig3).

Fig1. Sending a message

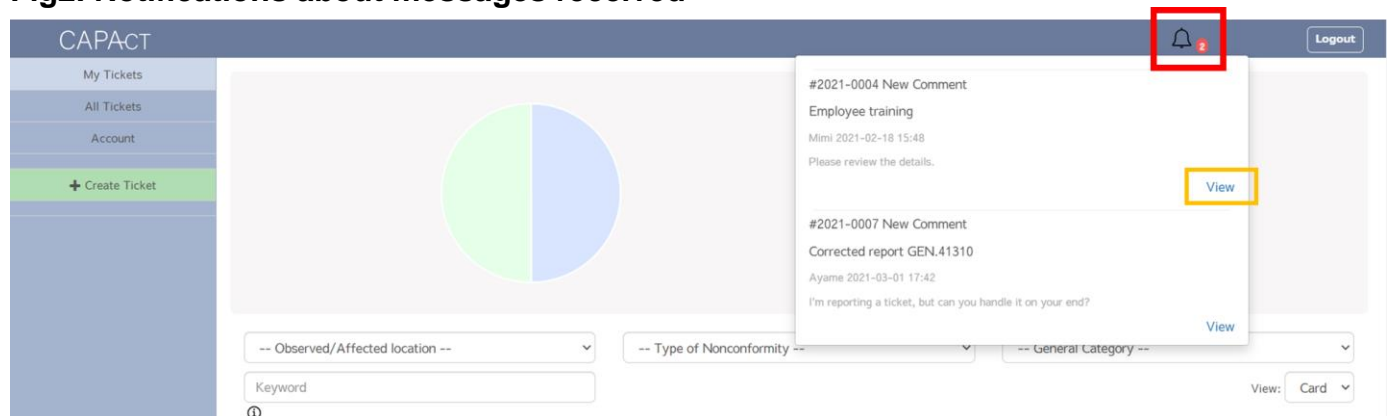
CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400



This screenshot shows the CAPAct user interface. On the left is a sidebar menu with options: My Tickets, All Tickets, Contents, Users, Logs, Account, and a green button for '+ Create Ticket'. The main area has a top header with 'CAPACT', a bell icon, and a 'Logout' button. Below the header is a large empty box with a paperclip icon and an 'Approve' button. To the right of this box is a red-bordered menu with 'Details', 'Comments', and 'Log' options, and buttons for 'Archive' and 'Excel output'. In the center, there's a 'Add To' dropdown menu with options: Ayame, Chacha, Chocolat, and Coo. Below it is a text input field containing 'I'm reporting a ticket, but can you handle it on your end?' and a yellow-bordered 'Send' button. At the bottom, there's a status bar with 'Ongoing', 'Due Date : TBD', and a 'Save' button.

Fig2. Notifications about messages received



This screenshot shows the CAPAct user interface with a notification popup. The notification popup is a white box with a red-bordered bell icon in the top right corner. It contains two notifications: '#2021-0004 New Comment' with details 'Employee training', 'Mimi 2021-02-18 15:48', and 'Please review the details.'; and '#2021-0007 New Comment' with details 'Corrected report GEN.41310', 'Ayame 2021-03-01 17:42', and 'I'm reporting a ticket, but can you handle it on your end?'. Each notification has a yellow-bordered 'View' button. The background shows the same CAPAct interface as the first screenshot, but with a pie chart in the main area and a search bar at the bottom.

CAPAct User Guide


FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

Fig3. Messages marked as read

Ayame 2021-03-01 17:42

To: Chacha ☑️ Coo

I'm reporting a ticket, but can you handle it on your end?

 Add To

Accessing the log for a single ticket (all users)

- 1) All changes to a ticket are recorded in the log. Simply click on “Log” in the right menu that shows up when you open a ticket. The log will indicate when changes are made as well as who made them and the details of what was updated/changed.

CAPACT

My Tickets

All Tickets

Contents

Users

Logs

Account

+ Create Ticket

<

Archiving tickets (Master Users only)

- 1) Master users have the ability to archive tickets whenever needed. Simply click on the “Archive” button on the right side at the bottom of the ticket detail (indicated in red). A warning sign will appear

CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

as archiving a ticket cannot be undone. Archiving a ticket will remove the ticket from the main dashboard unless otherwise indicated in the advanced search section.

The screenshot displays the CAPAct web application interface. On the left is a vertical navigation menu with options: My Tickets, All Tickets, Contents, Users, Logs, Account, and a green button labeled '+ Create Ticket'. The main content area is titled 'Evaluating Efficacy of Action' and features a large text input field. Above this field is a 'Due Date' selector with a calendar icon. Below the text field is an 'Approve' button with an information icon. To the right of the main area is a sidebar with links for 'Details', 'Comments', and 'Log'. At the bottom right of the sidebar, there is a red-bordered 'Archive' button and an 'Excel output' button. The bottom of the interface shows a status bar with 'Ongoing', 'Due Date : TBD', and a 'Save' button.

Accessing the log for the entire organization (Master Users only)

- 1) A summary of all changes made to tickets created within the organization is provided on the Logs dashboard. Simply click on “Logs” in the left menu. The log will indicate when changes are made as well as who made them as well as the general change made and to what ticket these changes were made.

CAPAct User Guide

FOS: CAP Nonconformity & Corrective Action / GEN.20208, GEN.20310, GEN.20318, GEN.20325, GEN.20327, GEN.23584, GEN.40492, GEN.41500, GEN.43035, GEN.43037, GEN.43335, GEN.57000, GEN.62020, GEN.76720, DRA.10440, DRA.10445, DRA.10460, DRA.11400

CAPAct

My Tickets

All Tickets

Contents

Users

Logs

Account

+ Create Ticket

-- User --

-- Operation type --

From:
年 / 月 / 日

To:
年 / 月 / 日

Date/Time	User Name	Operation	Report #	Title
2021-03-01 18:26	Ayame	FileUpload	2021-0004	Employee training
2021-03-01 18:24	Ayame	Edit	2021-0004	Employee training
2021-03-01 18:13	Chacha	Approve	2021-0001	ANP.10038 Client A tissue quality
2021-03-01 17:59	Chacha	Edit	2021-0001	ANP.10038 Client A tissue quality
2021-03-01 17:42	Ayame	PostComment	2021-0007	Corrected report GEN.41310
2021-03-01 17:29	Ayame	Create	2021-0007	Corrected report GEN.41310
2021-03-01 16:46	Ayame	Edit	2021-0006	Trying out new features.
2021-03-01 16:45	Ayame	Edit	2021-0004	Employee training
2021-02-18 15:48	Mimi	PostComment	2021-0004	Employee training
2021-02-05 13:21	Mimi	Archive	2021-0005	dddd
2021-02-05 09:33	Chacha	PostComment	2021-0006	Trying out new features.
2021-02-05 09:32	Chacha	Create	2021-0006	Trying out new features.
2021-02-05 09:25	Ayame	Approve	2021-0002	GEN.20325 STAT Test TAT Client A