OpenRIMS. Workflow Manual

Here you can find manuals that will help to create clear and high-quality workflows.

Contents

Step 1. Select a goal and the name of the Workflow

OpenRIMS allows such goals of workflow for a permit given

1. Apply for a permit (aka Guest)
2. Collect additional data (aka Host)
3. Modify permit data (aka Amendments) - Optional
4. Close a permit (aka De-registration)
5. Pre-inspection (aka Inspections) - Optional
6. Revoke a permit (aka Shutdown)

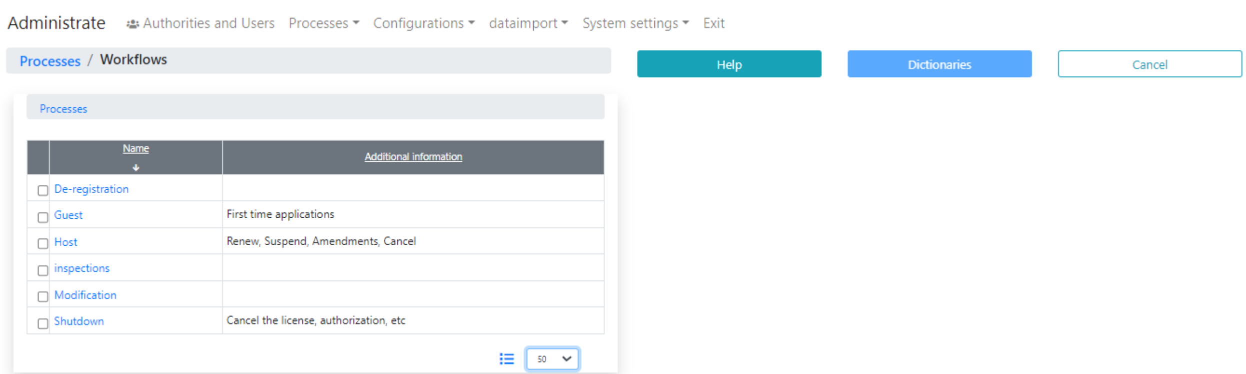

Figure 1 The Goals

1. Determine the permit, for example, “Medicine marketing authorization”
2. Determine the goal, for example, “Apply for a permit”
3. The workflow name will be “Apply for medicine marketing authorization”

Please note:

- For “Collect additional data” the workflow name will be a goal of data collecting, for example, “Renew the medicine marketing authorization”
- For “Modify a permit data” the modification should be included. For example, “Amend the final product manufacturer in the medicine marketing authorization”

Step 2. Define the Main Workflow Parameters

Where to start?

After goal selection, the OpenRIMS will provide a list of workflows that are existing for a selected goal

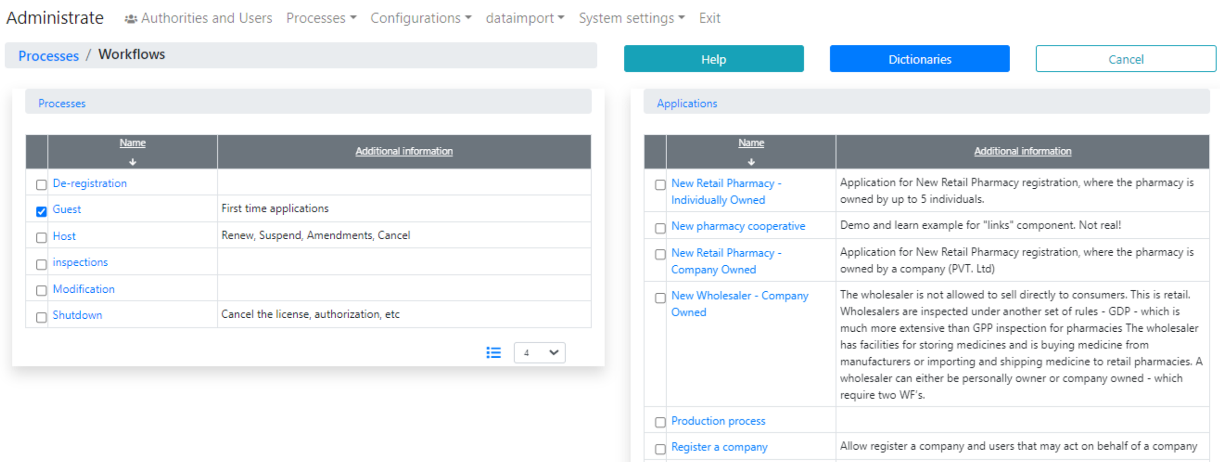

Figure 2 In the right table are workflows for the goal selected

Press “Dictionaries” to add a new workflow or modify the parameters for the existing one.

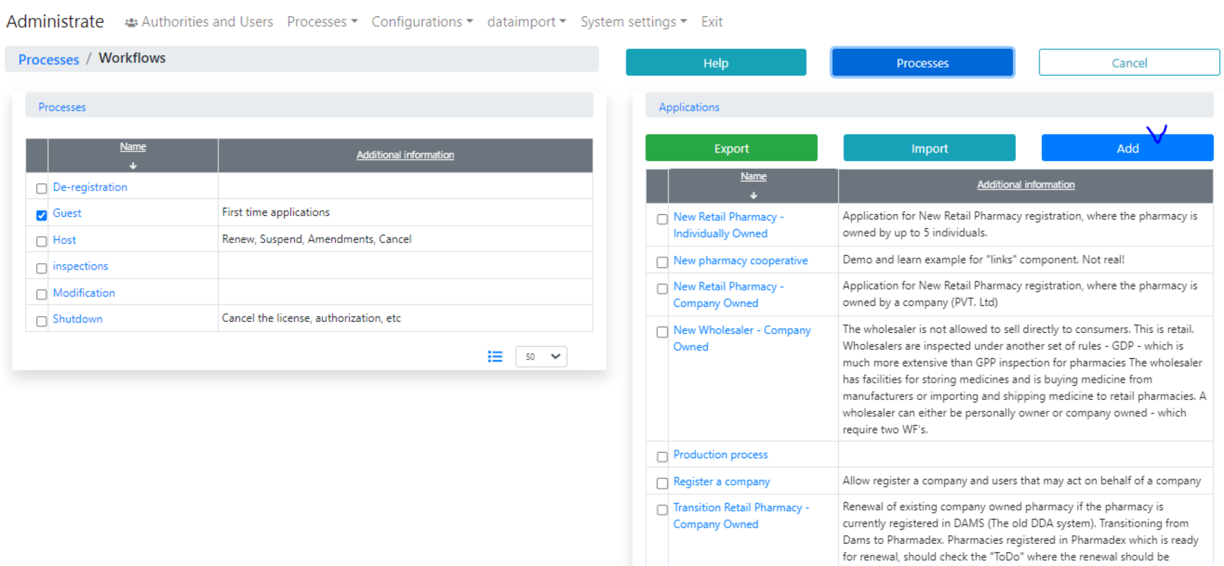

Figure 3 Add a new workflow for the goal selected

The electronic form to define workflow parameters depends on the goal selected:

1. Apply for a permit (aka Guest)
2. Collect additional data (aka Host)
3. Modify permit data (aka Amendments) - Optional
4. Close a permit (aka De-registration)
5. Pre-inspection (aka Inspections) - Optional
6. Revoke a permit (aka Shutdown)

The Parameters for Various Workflow Goals

Apply for a permit (aka Guest)

Examples are:

- Apply for medicine product marketing
- Apply for pharmacy business
- Apply for an import permit

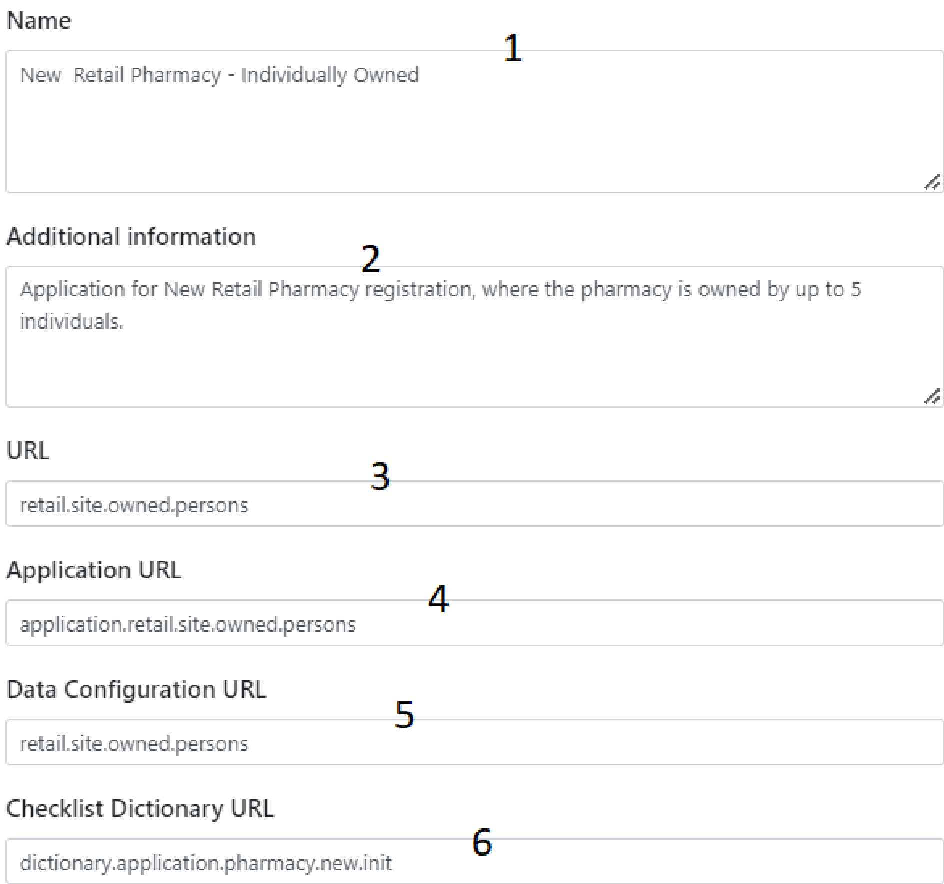

Figure 4 Parameters for "Apply for a permit" workflows

1. Name of the workflow. This name will be shown to an applicant for selection as well as in reports
2. Additional information describes the particularities, conditions, etc. It helps an applicant to select the right workflow.
3. URL of the application electronic form. Under this URL the application will be stored in the database. Because the application electronic form is unique for each workflow, this URL will be used in reports to distinct permits, e.g., permits for pharmacy business from medicine marketing authorization permits
4. URL to distinct sets of activities. It is possible to share the same set of activities between workflows.
5. Should be the same as the URL of the application electronic form.
6. URL of a dictionary that is used as a self-checklist while submitting an application

Collect additional data (aka Host)

Additional data are data collected while a permit lifecycle. Examples are:

- Scheduled Renewal of a permit
- Schedule an inspection
- Conduct an inspection

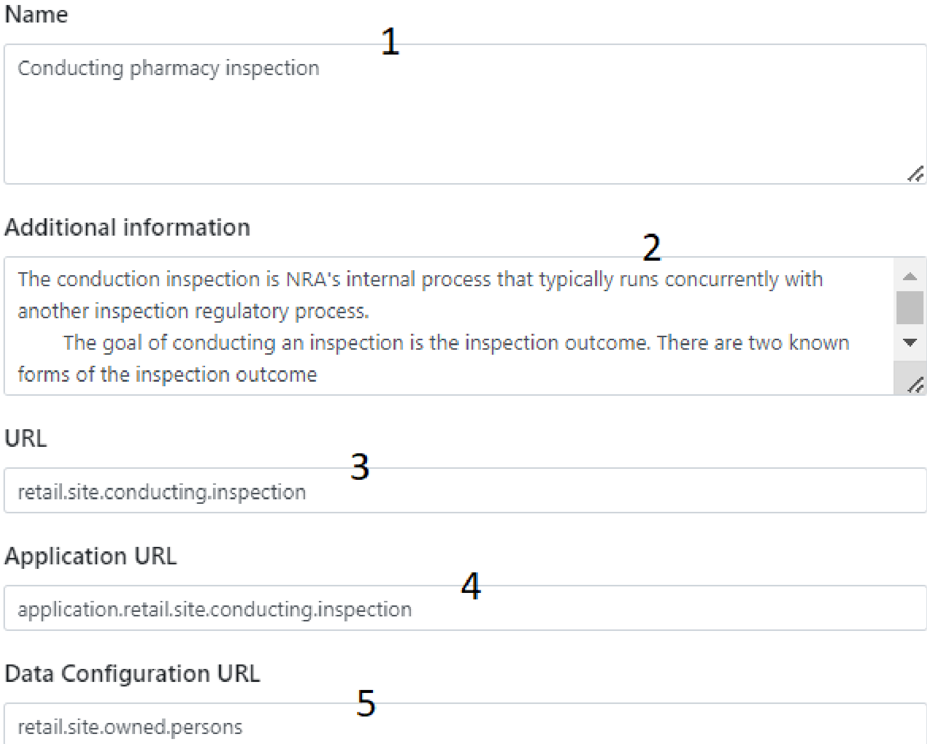

Figure 5 Parameters for the "Collect additional data"

1. Name of the workflow. This name will be shown to an applicant for selection as well as in reports
2. Additional information describes the particularities, conditions, etc. It helps an applicant to select the right workflow.
3. Unique URL for this workflow. This parameter is for reporting to distinct workflows each other.
4. URL to distinct sets of activities. It is possible to share the same set of activities between workflows
5. Empty or URL of the application electronic form. Define this parameter to allow running this workflow manually using the Monitoring feature

Modify permit data (aka Amendments)

Examples are:

- Amend the owner of the pharmacy business
- Amend the final product manufacturer in the medicine marketing authorization
- Amend a quantity in the import permit

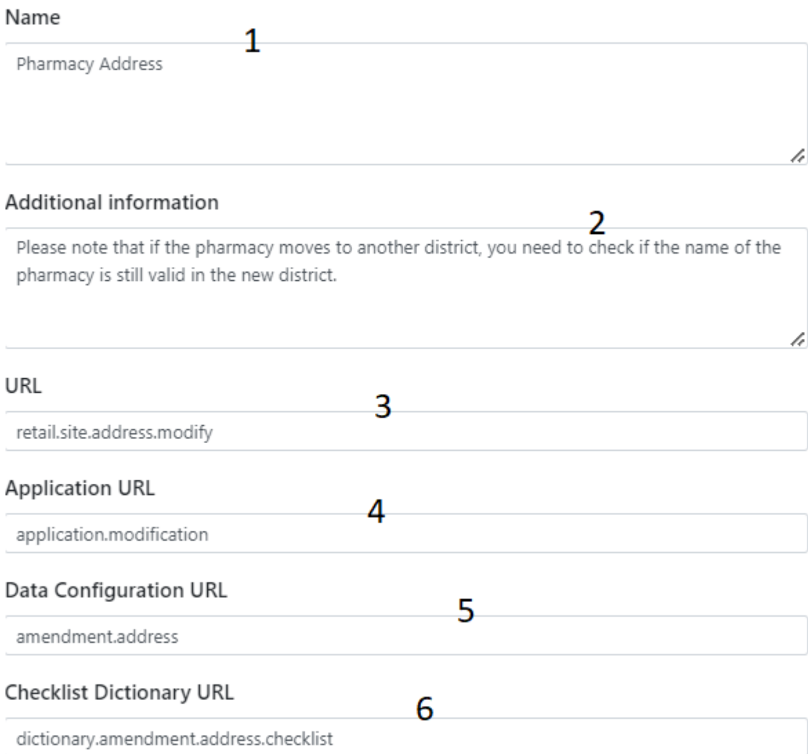

Figure 6 Parameters for "Modify a permit data" workflows

1. Name of the workflow. This name will be shown to an applicant for selection as well as in reports
2. Additional information describes the particularities, conditions, etc. It helps an applicant to select the right workflow.
3. The URL of the modification electronic form.
4. URL to distinct sets of activities. It is possible to share the same set of activities between workflows Modification application electronic form configuration URL
5. Checklist Dictionary URL defines a dictionary that is used as a self-checklist while submitting an application

Close a permit (aka De-registration)

Examples are:

- Close pharmacy business
- Close medicine marketing authorization
- Close import permit

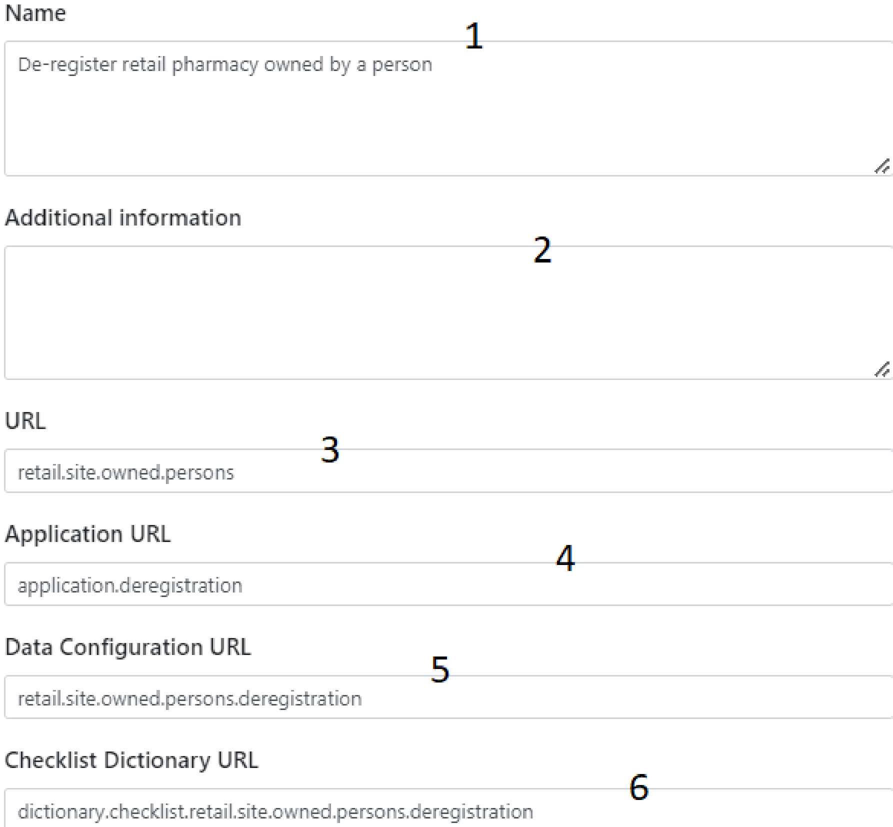

Figure 7 Parameters for "Close a permit" workflows

1. Name of the workflow. This name will be shown to an applicant for selection as well as in reports
2. Additional information describes the particularities, conditions, etc. It helps an applicant to select the right workflow.
3. URL of the application electronic form. This URL defines which permit should be closed
4. URL to distinct sets of activities. It is possible to share the same set of activities between workflows.
5. Close a permit application electronic form configuration URL
6. Checklist Dictionary URL defines a dictionary that is used as a self-checklist while submitting an application

Pre-inspection (aka Inspections)

Also, can be used for follow-up inspections. Examples are:

- Pre-inspect a pharmacy
- Pre-inspect a medicine batch for import

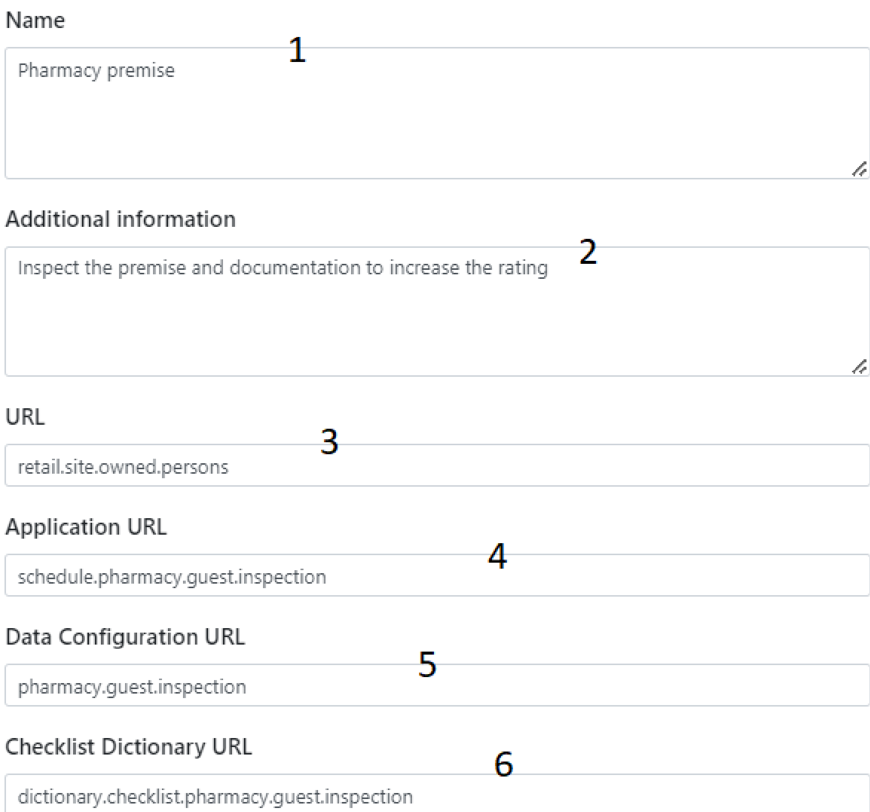

Figure 8 Parameters for "Pre-Inspection" workflows

1. Name of the workflow. This name will be shown to an applicant for selection as well as in reports
2. Additional information describes the particularities, conditions, etc. It helps an applicant to select the right workflow.
3. URL of the application electronic form. This URL defines which permit should be inspected
4. URL to distinct sets of activities. It is possible to share the same set of activities between workflows.
5. Pre-Inspection application electronic form configuration URL
6. Checklist Dictionary URL defines a dictionary that is used as a self-checklist while submitting an application

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Revoke a permit (aka Shutdown)

Permit revocation also can be used for permit suspension. Examples are:

- Revoke medicine marketing authorization
- Revoke pharmacy business permit
- Revoke import permit

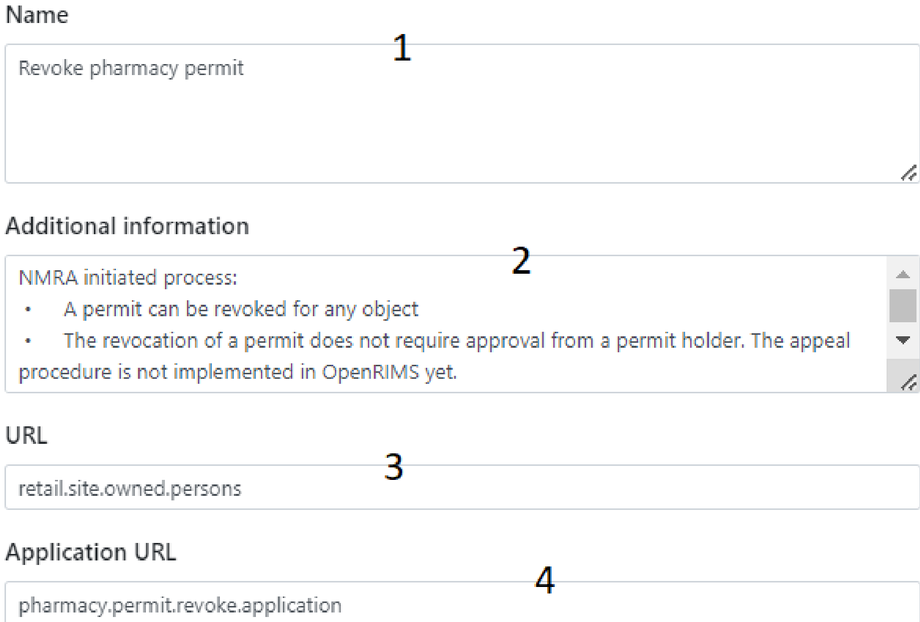

Figure 9 Parameters for "Revoke a permit" workflows

1. Name of the workflow. This name will be shown to an applicant for application selection as well as in reports
2. Additional information describes the particularities, conditions, etc. It helps an applicant to select the right workflow.
3. URL of the application electronic form. This URL defines which permit should be revoked
4. URL to distinct sets of activities. It is possible to share the same set of activities between workflows.

Step 3 Define data to collect

The Initial Data, i.e., the Application Electronic Form

Workflows with goals “Apply for a permit”, “Modify a permit data”, “De-register a permit” and “Pre-inspection” start by a business. The Business should fill out an electronic application form and send it to the National Regulatory Authority.

The existing paper or electronic application is a good starting point. Refer to [How to design the Application Electronic Form?] for more information.

The information from this form can be used for application processing, review, reporting, and document generation.

A typical application form consists of pages. Examples are below:

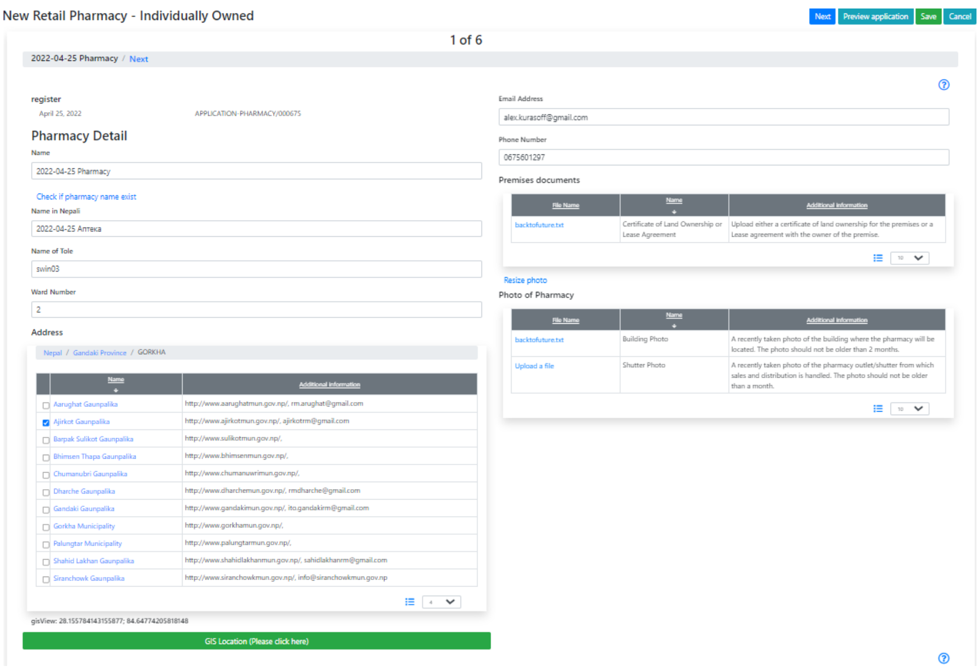

Figure 10 An example of the first page of an application form allows to input general application data

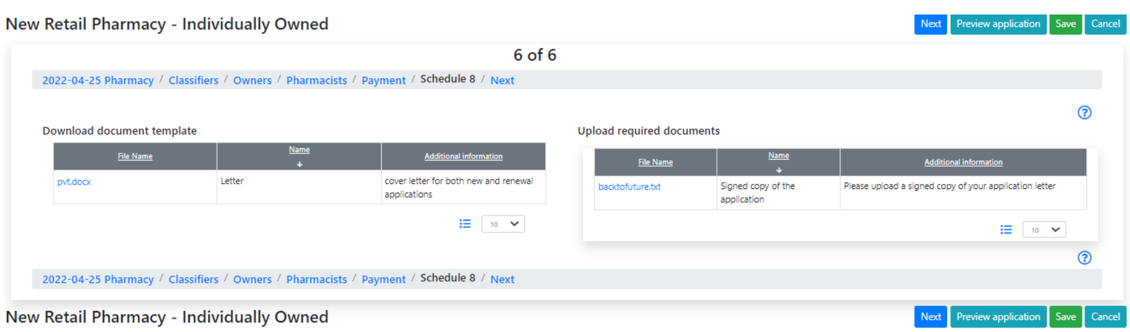

Figure 11 An application electronic form typically consists of many pages to allow the application to be convenient and modifiable

The Additional Data, i.e., the Activity Electronic forms

Workflow activity is a unit of work that should have an outcome. The outcome consists of:

- The checklist to ensure that the activity is processed properly
- Data that should be collected for the permit (optionally)
- Next action

In case an activity should collect data, an activity electronic form should be created. It should be a single–page electronic form that typically contains:

- Static texts and/or web links, aka “headers”
- Text, number, and logical fields
- Dates or dates intervals
- Registers to maintain electronic office journals
- Dictionaries and droplists to classify the application data
- Schedulers to run “Collect an additional data” workflows
- Resources to download and auto-generate electronic documents
- Documents to upload/download electronic documents and files

The information from this form can be used for application processing, review, reporting, and document generation.

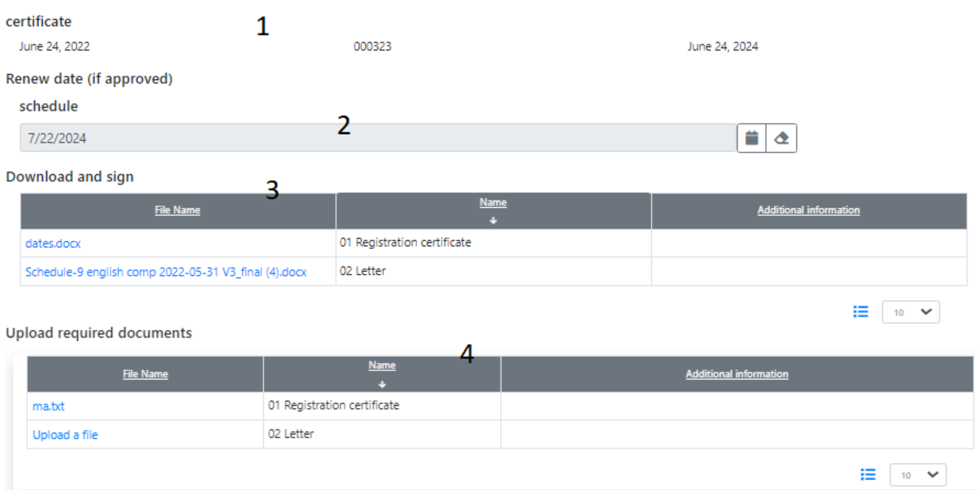

Figure 12 An activity electronic form example

1. Register the certificate issued
2. Schedule the certificate renewal
3. Generate electronic documents
4. Upload official documents

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Step 4 Define workflow activities

Where to start?

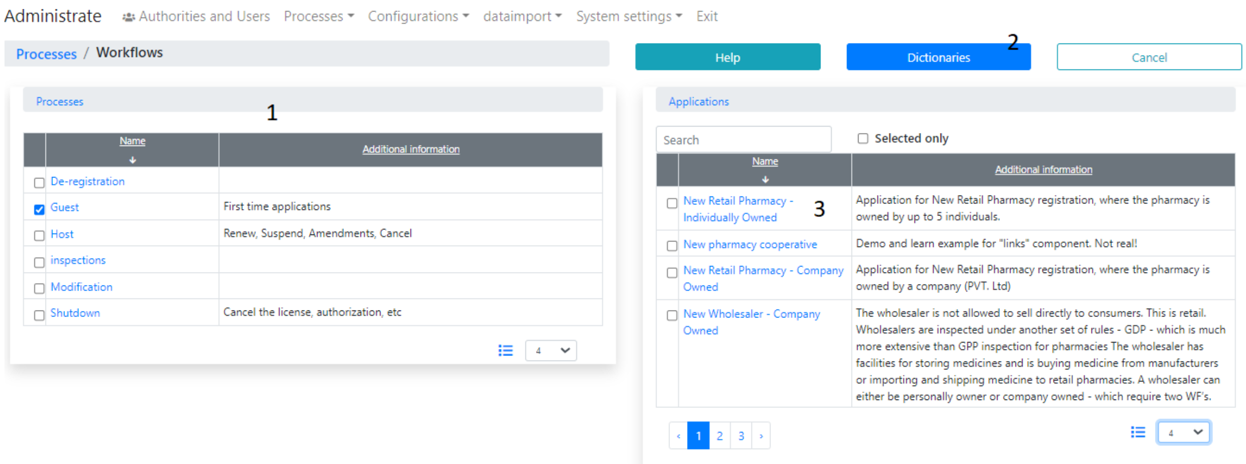


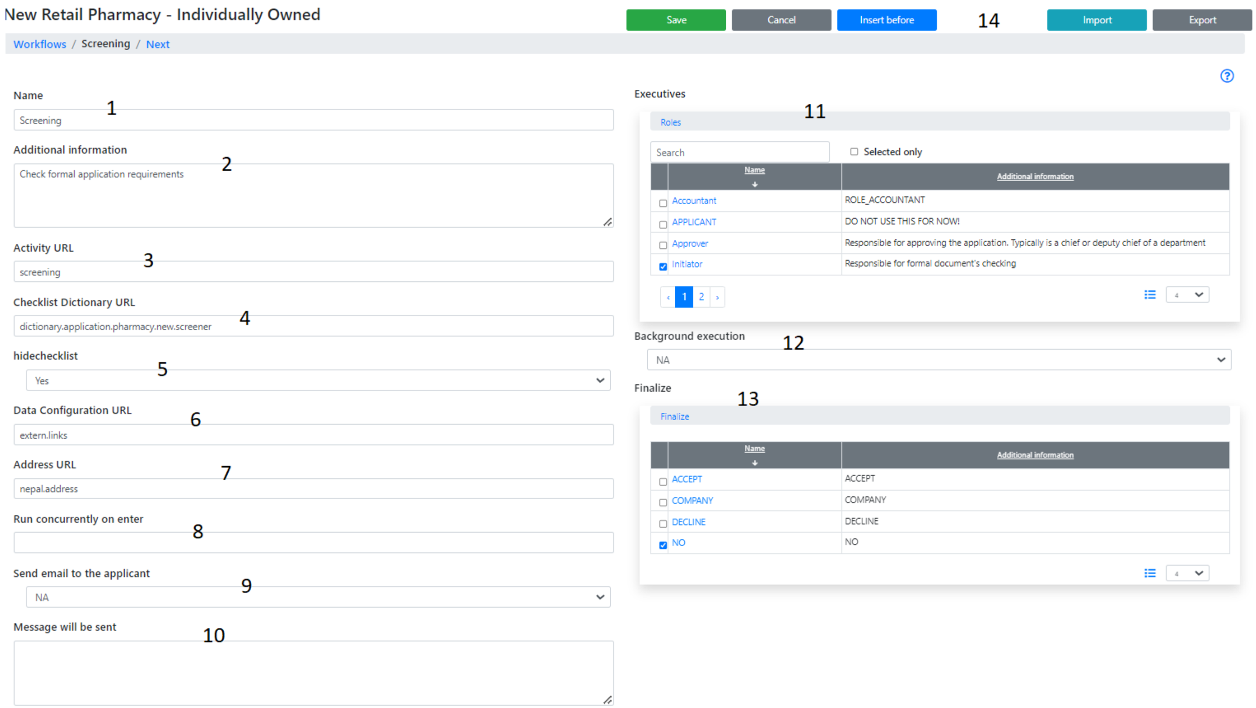
Figure 13 Start workflow definition

1. Select a goal
2. Ensure that the button is "Dictionary"
3. Find the workflow in the list and click on it. If the workflow is absent, then return to [Step 2. Define the Main Workflow Parameters]
4. Should be opened the Activity Definition Form contains controls on the top:

Figure 14 Workflow definition controls

1. Return to the "Start workflow definition" screen
2. Name of the activity currently
3. Save this activity and, go to the next activity/add a new activity. New added activity will not be saved at once
4. The toolbar:
   4.1. Save the current activity
   4.2. Cancel without saving
   4.3. Insert an activity before the current one
   4.4. Import all activity definitions to the MS Excel file
   4.5. Export all activity definitions from the imported MS Excel file
5. Get a brief help for mandatory form fields
6. The following activities in this place will be the "Remove Activity" button. It is impossible to remove the first activity.

Activity definition form



1. Visible name of the activity, e.g., “Screening”, “Review”, “Solution”, etc.
2. Description of the activity, currently only for an internal purpose
3. Activity will be stored under this URL. It will be a good idea to make this URL same very similar or the same as “Name”
4. The dictionary that contains the checklist definition
5. The checklist may contain sensitive information, thus hidden from the applicant
6. The electronic form for this activity
7. Works only for the first activity. If empty, the first activity will be processed by the Main Office, otherwise by the Branch Office.
8. URL of workflow that should run concurrently with this activity, just after the activity will be started
9. Will email notifications be sent?
10. Text of the email notification. The link to the Permit Data will be included
11. User role to process the activity
12. Is this activity will be processed in the background?
13. Which items will be in the Activity Submit actions?
14. The following activities in this place will be the “Remove Activity” button. It is impossible to remove the first activity.

Tips and tricks

How to design the Application Electronic Form?

1. Application electronic form may be multi-page
2. The first page must contain the text field “prefLabel”
3. Split the form into pages using the following hints:
    3.1. Determine all possible modification
    3.2. For each modification outline the electronic form
    3.3. Place on one page all components that can be modified and, additional if ones.
4. Many pages with a little number of components on each are better compared to a little number of pages with a lot of components on each
5. The reasonable number of pages is up to five
6. Use the “persons” component to allow an undefined number of information blocks with the same structure and/or complex multi-pages information blocks, e.g., pharmacy owners, wholesaler warehouses, manufacturer’s premises
7. Use the “links” component to allow usage in application form already registered permits, e.g., valid medicine manufacturers, medicines allowed for marketing, INNs allowed to use, and legacy permit data.

Consider the following example:

Suppose a form to apply for a retail pharmacy business. The paper form contains name, address, owner’s data, business state registration documents, premise data, and premise documents. It is possible to change the address. Thus, the following pages look good:

- Name, owner
- Business state registration documents
- Premise address and documents

Despite the owner may be one, the owner data may be complex, thus multi-pages. It will be a good idea to use the “persons” component for the owner.

The “links” component is not appropriate for this example.

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How to create a checklist?

For an applicant, the electronic checklist allows self-evaluating the application against formal National Regulatory Authority requirements.

For a workflow activity, the electronic checklist allows self-evaluating the outcome of the activity against standards and rules.

It should be noted that checklists are available only for review, and for document generation and reporting. OpenRIMS separates data collecting and data evaluation jobs.

For example, a formal requirement for CTD Module 2 review is

INTRODUCTION

2.3.S DRUG SUBSTANCE (NAME, MANUFACTURER)

2.3.S.1 General Information (name, manufacturer)

Information from 3.2.S.1 is included.

After the formal requirements will be formulated and approved, it should be entered into a new dictionary using Administrate-Configuration-Dictionaries

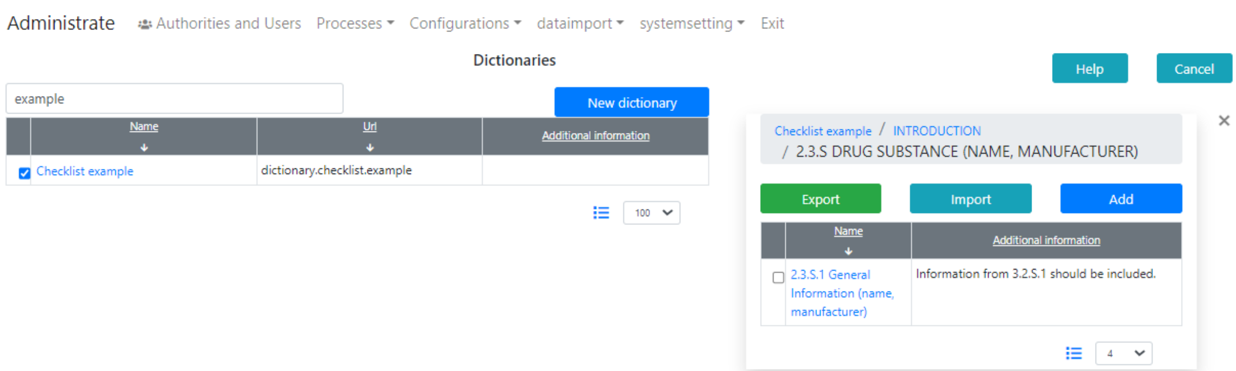

Figure 15 Checklist dictionary example

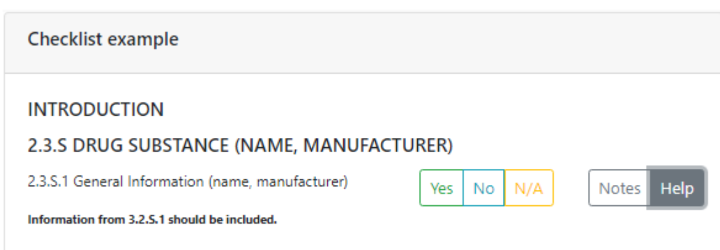

Figure 16 Checklist example

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How to run workflows?

A workflow is considered as running if at least one activity of it is not completed. A workflow starts from the first activity.

Workflows “Apply for a permit (aka Guest)”, “Modify a permit data (aka Amendments)”, “Close a permit (aka De-registration)”, and “Pre-inspection (aka Inspections)” are applications that a business applicant starts

Workflow “Collect an additional data (aka Host)” can be started:

- By schedule, as configured by the “schedules” component
- When some activity will be started, as defined in the Activity Definition Form
- Manually by “Moderator” or “Supervisor if allowed by the Activity Definition Form

Workflow “Revoke a permit (aka Shutdown)” can be started

- When some activity will be started
- Manually by “Moderator” or “Supervisor

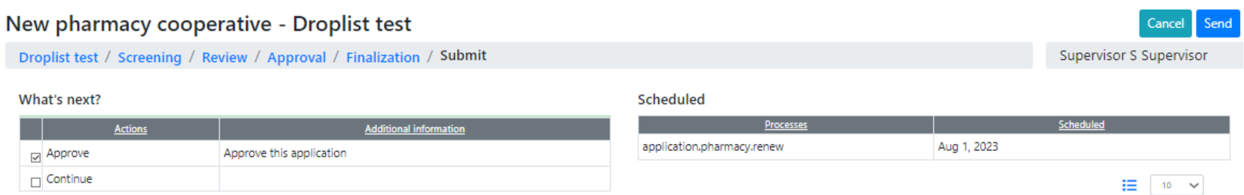

Figure 17 Run the "Renew" application by schedule

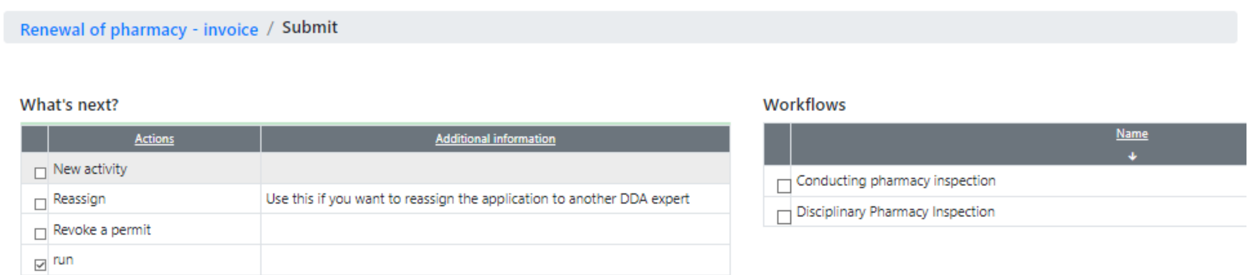

Figure 18 Run inspections manually by the moderator using the "Monitoring" feature. Please, put your attention on the “Revoke a permit” action

How to design an application electronic form for the Modification Application?

Modification application allows an applicant to apply for minor changes to the permit data without the necessity to get a new permit. Changes can be applied to data defined on any page of the Application Electronic form

The minimal electronic form for modification application typically consists of two pages:

1. The main page must contain the read-only field “prefLabel” and, possibly, additional fields, classifiers, and documents necessary to apply for a modification
2. The modification page should contain components same classes and names as components on some pages of the Permit Application Electronic form

An example of the “Modify Pharmacy Owner” application

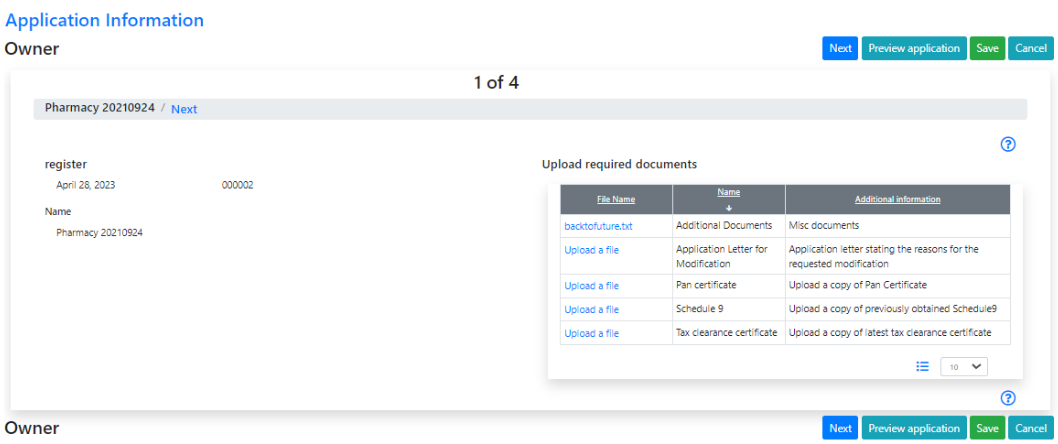

Figure 19 Main page of the modification application contains register, prefLabel, and documents

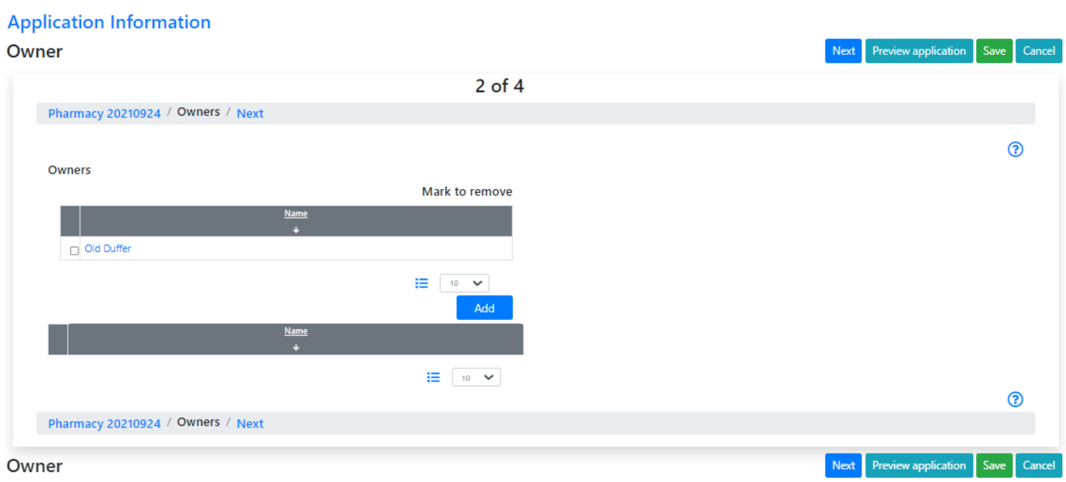

Figure 20 Modification page contains the component "person" with the name "Owner". It allows modifying the Owner's data in the permit

How to design an application electronic form for the Close a Permit Application?

The Permit is considered closed when the permit owner has decided it and National Regulatory Authority confirmed it. To close a permit the owner should apply to National Regulatory Authority.

The minimal electronic form for the “Close a Permit (aka De-Registration)” application may consist of one main page. This page should contain a read-only “prefLabel” field, and, possibly, additional fields, classifiers, and documents necessary to apply for permit closing.

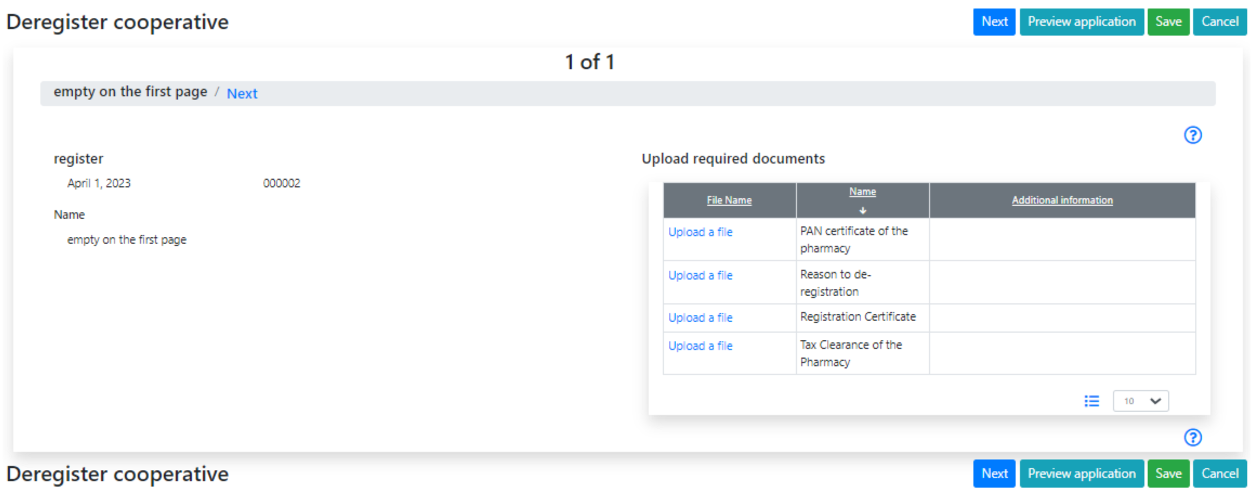

Figure 21 Close application main page example

How to design an application electronic form for the Pre-Inspection Application?

An applicant can apply for pre-inspection of the business, before applying for a permit. Additionally, an applicant can apply for a follow-up inspection of the business to improve the business rating.

The minimal electronic form for the "Pre-inspection (aka Inspections)" application may consist of one main page. This page should contain a read-only "prefLabel" field, and, possibly, additional fields, classifiers, and documents necessary to apply for pre-inspection/follow-up inspection.

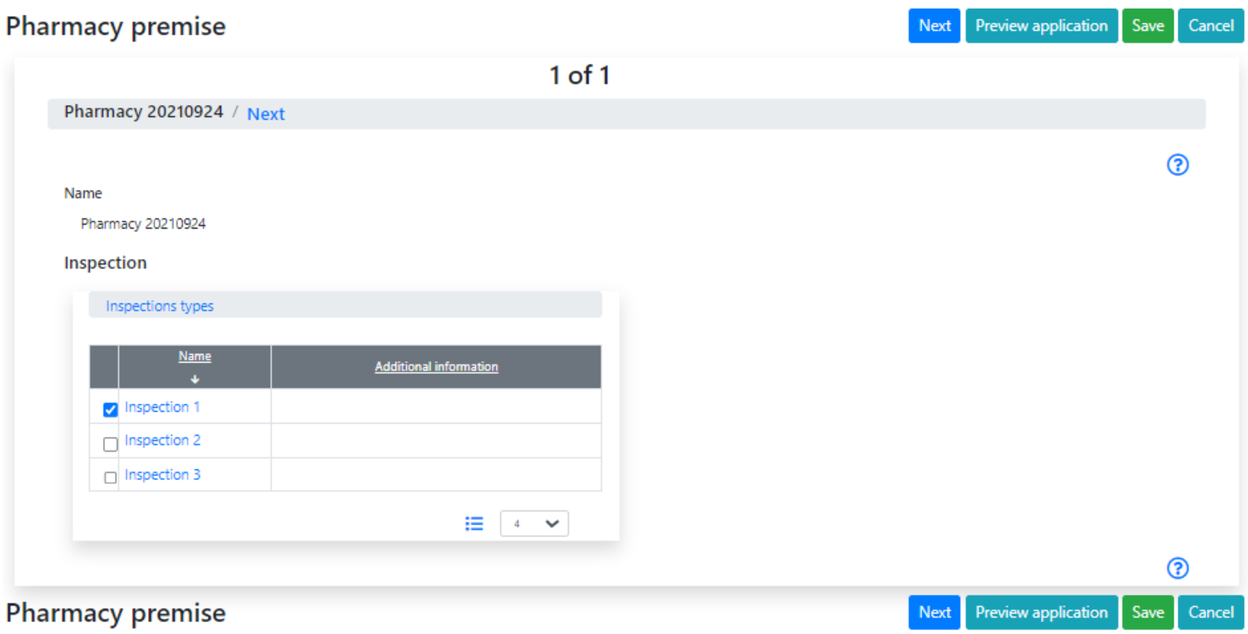

Figure 22 Pre-inspection electronic form main page example

What is the difference between closed and revoked permits?

Any permit can be revoked or suspended by National Regulatory Authority. The revocation invalidates the permit, however, allows the business to fix the cause and apply again.

Unlike revoked, the permit is considered closed when the permit owner has decided it and National Regulatory Authority confirmed it. The closed permit cannot be applied again.

How to review the information collected?

For any given permit, OpenRIMS collects application data, and additional data collected in all workflows related to a permit.

This information is available for review in the application dashboard, To Do and Monitoring lists, and in publicity available electronic forms.

To determine access to the information collected OpenRIMS applies the following rules:

1. Only public information from closed and valid permits is publicity available
2. For an NRA employee access restricted by workflows allowed
3. Applicants can fully access all own permits

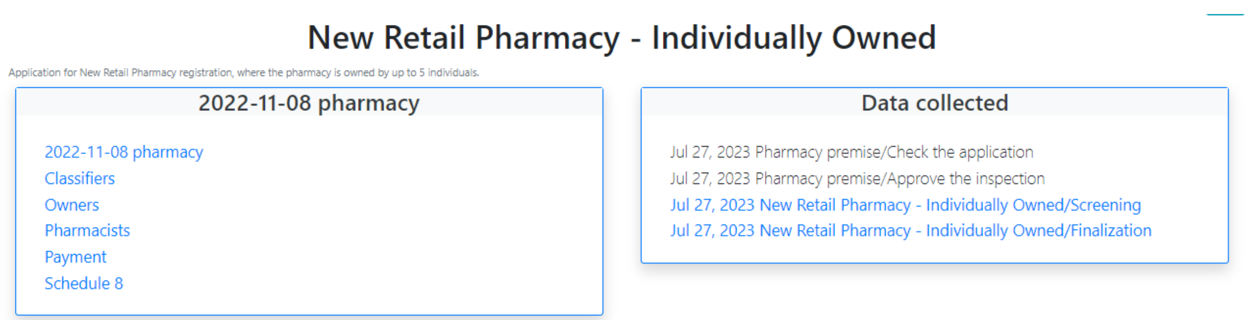

Figure 23 This form is used by the Application Dashboard, Monitoring All, and Publicity Available. Click on the link to expand

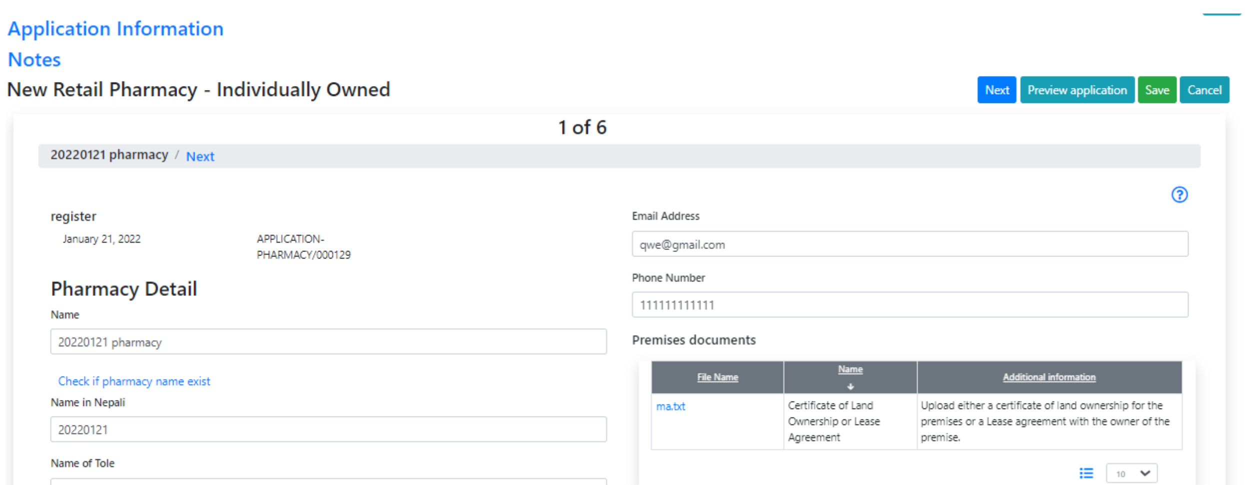

Figure 24 This form is used by Do and Monitoring lists. Click on Application Information to review the data collected by workflows

Which action should be selected for the activity?

When the executor submits an activity, OpenRIMS proposes a set of actions. Actions “Continue” and “New activity” are always available. The action “Continue” allows the selection of the next activity and an executor of it. The action “New activity” allows the run of any available activity concurrently with the current one.

The activity configuration allows adding other actions using the “Finalize” section

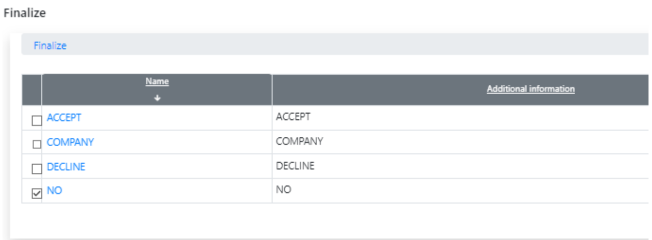

Figure 25 The "Finalize" section in the activity configuration form

- “No” will not add any actions
- “ACCEPT” adds the action “Approve”. This action finalizes the workflow. The selection of this action is the same as stamping “Approved” on a document.
- “COMPANY” adds the action “Approve”. It is a special case only for company registration workflows
- DECLINE adds action “Decline”. This action finalizes the workflow. The selection of this action is the same as stamping “Decline” on a document.

It is possible to customize and translate names of “Finalize” choices in the activity configuration using dictionary “dictionary.system.finalization”

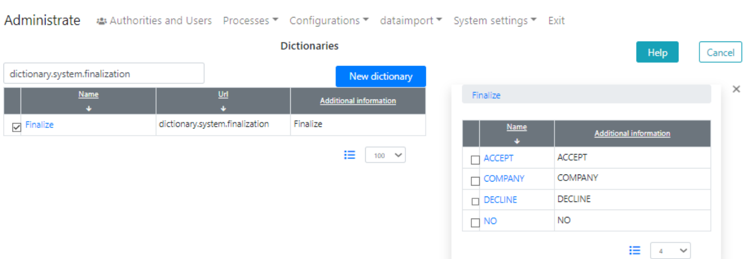

Figure 26 Finalization actions dictionary

It is possible to customize and translate names of action using the Administrate-Processes-Actions feature

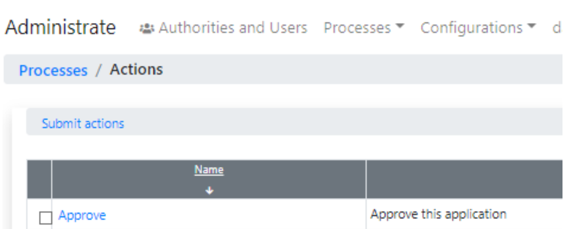

Figure 27 Administrate-Processes-Actions feature allows customizing and translation names of activity submit actions

How to pass workflow to the Branch Office?

A workflow starts from the first activity. The NRA executors will be selected using the following sequency:

1. Select the office – the main office or a branch office
2. Select employees in the selected office that suit workflow access rules and role
3. If any executor had been found, select Secretary in the selected office that has access to the workflow
4. If executors are still not found, select Supervisors in the main office
5. In case any executor has been found, the activity doesn't start

The office selection depends on the field "Address URL" in the activity configuration. If this URL is empty, the main office will be selected, otherwise, the office that serves the address from the application electronic form.

For example

- The Address URL in the configuration of the first activity is "premise.address"
- The activity executors will be selected from the Branch Office that is serve the district or province listed in the address defined anywhere in the application electronic form under the URL "premise.address"

The territory served by the office may consist of first-level administrative units (provinces) or second-level administrative units (districts). Search for details in the documentation or ask the community for help.

Workflow access and roles are defined individually for each NRA employee in the feature "Administrate-Authorities and users

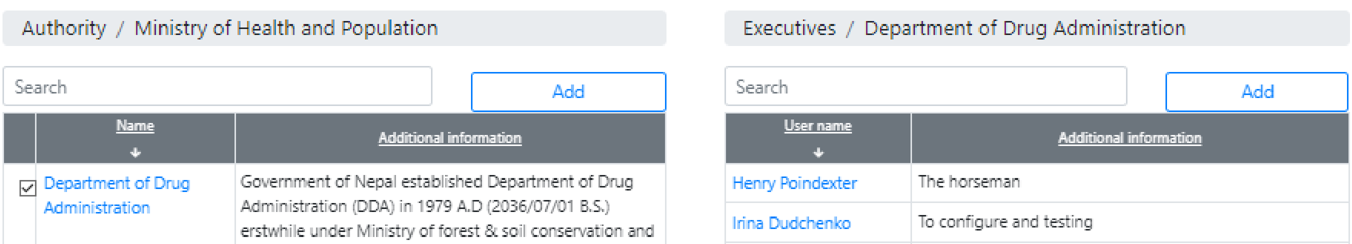

Figure 28 Office, Roles, and workflow access are defined individually for each NRA employee

The fallback executor selection procedure will be necessary to avoid excess system management complexity:

1. The office secretary is always responsible for the incoming application and can re-route it to the right executor.
2. The central office supervisor can re-route it to the right office secretary and fix the issue

It is possible when the first activity will be assigned concurrently to many executors. For the first activity, the first finished activity will win, and the rest will be canceled. Thus, it is impossible to execute the first activity concurrently.

What is background activity?

A background activity intends to collect data out of the workflow's sequency. For example, payment confirmation, validation of documents, etc.

A background activity starts when the first activity starts and can be completed at any time.

A background activity does not allow actions after completion.