

OpenRIMS. Workflow Manual

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

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Planning

Organization Maturity Level

OpenRIMS is workflow automation software. The workflow automation implementation depends on the Regulatory Authority's maturity level.

The Regulatory Authority maturity model defines several levels or stages that an organization can progress through, such as:

1. **Initial/Ad-hoc:** Processes are ad-hoc and disorganized. There is a lack of defined processes and procedures.
2. **Managed:** Processes are defined and documented. There is some level of process management and control.
3. **Defined:** Processes are standardized, documented, and integrated across the organization. There is an emphasis on continuous improvement.
4. **Quantitatively Managed:** Processes are measured and controlled. Data is used to make informed decisions about process improvements.
5. **Optimizing:** The organization focuses on continually improving process performance through incremental and innovative technological changes and improvements.

The OpenRIMS is designed for levels 2, and 3 and provides a good starting point for level 4. For level 1 it will be necessary to define and document processes before. The OpenRIMS software can help do the job by providing good practices and the low-expensive possibility to define processes before approval

Workflows

An applicant needs a permit to do activities related to medical products and devices. To receive a permit, the applicant should submit the application to the National Regulatory Authority (NRA) for approval. NRA can approve or decline an application.

An approved application may be renewed, inspected, revoked, modified, and de-registered.

From the Regulatory Authority's point of view approving, renewing, inspecting, revoking, modifying, and de-registration are workflows. The OpenRIMS is a tool to automate them.

The automation of a workflow in OpenRIMS provides:

1. **A sequence of activities:** A workflow outlines the specific activities that need to be taken to complete a task or process:
 - 1.1. The first activity of a workflow is mandatory
 - 1.2. OpenRIMS advises the most common sequence of activities. Nevertheless, the NRA's executor can pass the workflow to any activity.
 - 1.3. NRA's executor can run the next activity concurrently for many executors. The decision of whether the concurrent job has been completed is manual.
 - 1.4. The workflow should contain at least one activity with an APPROVE outcome and may contain an activity with a DECLINE outcome
 - 1.5. For applicant-initiated workflows, it is possible to return the application to the applicant to fix minor inconsistencies. After the fixing, the application should re-apply from the first activity
2. **Defined responsibilities:** Workflow assigns ownership for an activity:
 - 2.1. The activity executor belongs to a role. The first activity may be assigned to an executor from the territory office.
 - 2.2. The NRA's executor should select executors of the next activity manually, from a list of possible executors provided by OpenRIMS

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- 2.3. It is possible to configure an applicant as an executor for an activity. Applicant cannot select an executor for the next activity
- 2.4. For any workflow should be assigned a moderator. The moderator is an NRA employee, that is responsible for:
 - 2.4.1. Assigning executors for important and concurrent activities
 - 2.4.2. Re-assigning executors for the stalled activities
 - 2.4.3. Decisioning whether the important or concurrent activities are completed properly
 - 2.4.4. Decision whether the workflow is completed or not.
3. **Automation:** Workflows can be automated using software to streamline processes and reduce manual effort:
 - 3.1. OpenRIMS advises a list of activities to complete a workflow
 - 3.2. OpenRIMS assigns executors for the first activity automatically.
 - 3.3. OpenRIMS proposes a list of executors of any activity. This list is compiled using the executor's role and access rights.
 - 3.4. OpenRIMS provides customized electronic forms with data input automation features and pre-filled electronic documents
4. **Visibility:** Workflows increase transparency by showing stakeholders the status of tasks and who is responsible for them:
 - 4.1. The Application History allows review:
 - 4.1.1. Outcomes of all activities
 - 4.1.2. All data collected
 - 4.1.3. All activities have been planned
 - 4.2. To-do list for workflow executors
 - 4.3. The Notes Submit feature allows passing the textual information to the next activity. All notes are stored in the Application History
 - 4.4. Optional email notification
 - 4.5. Monitoring list of activities to search for stalled workflows
 - 4.6. Allowance to use external BI software to collect the Key Performance Indicators as well as custom application tracking.

Tips and advice

The Secretary role is for the first and last activities

The first and final activities are typical responsibilities of the Secretary. A Secretary is the Front Office officer who accepts applications from the applicants and returns results to the applicants.

Additionally, a Secretary is responsible for:

- Running the second activity
- Reassigning an executor of an activity, if it will be needed
- Any collaboration with the applicant

The Moderator role is mandatory

At least one moderator should be assigned for any workflow. It is a conductor of a workflow that is responsible for orchestration:

1. Managing the sequence of activities, if necessary. It means checking the result of an activity or activity execution and assigning the next activity or returning to the previous one if the result is not satisfied.
2. Managing the completion of concurrent and important activities
3. Managing the completion of the workflow itself

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4. Monitoring execution of workflows
5. Reassigning an executor of an activity, if it will be needed

The Supervisor User shouldn't be the executor of an activity

A Supervisor can monitor the execution of workflows and reassign an executor of an activity if it will be needed Other workflow roles. Theoretically, the Supervisor can't perform any activity.

Starting conditions for the first activity

There are three ways to run a workflow:

- Applicant sends an application, e.g. "Medicinal Product Marketing Authorization"
- NRA selects an application and runs a workflow, e.g. "Suspending Marketing Authorization"
- By schedule after the approval of an application, e.g. "Renew the Marketing Authorization"

Regardless of the way to run, the first activity of a workflow will be started only if all the following conditions occur:

- The application data is valid
- The workflow is configured properly
- At least one executor of the first activity has been found

Executors of the first activity

OpenRIMS assigns executors for the first activity automatically using the following algorithm:

1. Apply territory office restriction if needed
2. Search for employees with the role noted in the activity configuration and for which access to the application is allowed
3. If not found – search for Secretaries for which access to the application is allowed
4. If not found – search for all NRA Supervisors for which access to the application is allowed

Applying territory office restriction for the first activity

The territory office restriction can be applied to a set of provinces or districts. To determine provinces or districts, the application.properties configuration parameter is used:

manage territory responsibility for NRA units

1 - provinces, 2 - districts

pharmadex.territory.responsible=2

The office configuration in Authorities and Users, Manage contains a list of allowed territories. Example is:

administrative	administrative
<input checked="" type="checkbox"/> Madhesh Province	SAPTARI
<input checked="" type="checkbox"/> Madhesh Province	SIRAH
<input checked="" type="checkbox"/> Province 1	BHOJPU
<input checked="" type="checkbox"/> Province 1	DHANKUTA
<input checked="" type="checkbox"/> Province 1	ILAM
<input checked="" type="checkbox"/> Province 1	JHAPA
<input checked="" type="checkbox"/> Province 1	KHOTANG
<input checked="" type="checkbox"/> Province 1	MORANG
<input checked="" type="checkbox"/> Province 1	OKHALDHUNGA
<input checked="" type="checkbox"/> Province 1	RANCHHAR

Figure 1 Territories that the office serves

An empty list means the whole country. Refer to the Activity Configuration electronic help for more information.

Completion of the first activity

Mostly, the OpenRIMS assigns a first activity to more than one executor. However, the first activity cannot be executed concurrently. After an executor completes the activity, OpenRIMS cancels the extra ones.

Which executor completes the first activity should be decided out the OpenRIMS.

Typical goals of the first activity are:

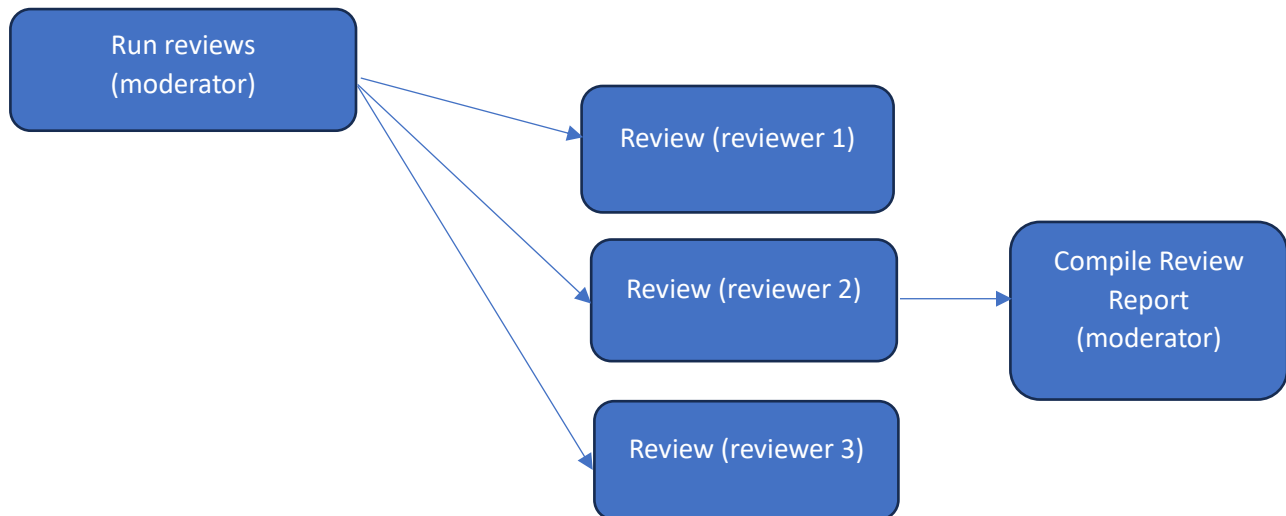
1. Assignment of the incoming number
2. Passing to the next activity/executor, usually a Moderator. The Moderator decides future activities and executors

Often, the first activity is used for the document screening.

Managing the completion of concurrent and important activities

Any activity, except the first and last can be run concurrently or execution of an activity is important for all workflow. It will be a good idea to involve the moderator to run these activities and check the execution of them.

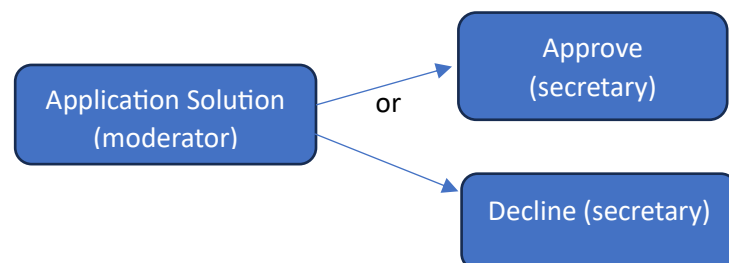
An example is below:



1. The Moderator runs three concurrent “Review” activities
2. Reviewer 2 has finished the job first
3. The OpenRIMS assigns to the Moderator the activity “Compile Review” after the first concurrent Review Activity will be submitted
4. For the rest, of the not-completed activities, OpenRIMS will not allow the next activity/executor assignment
5. The Moderator waits for the completion of other activities, using the Application History feature

Approve and Decline an application

The approval and decline of an application require the preparation of documents from the Registration Authority to the Applicant. It will be a good idea to assign this activity to the Secretary, however the decision should be performed by the Moderator.



Asking the applicant for additional data

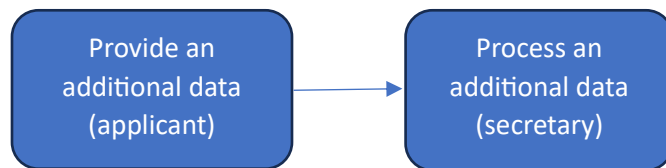
Sometimes it will be necessary to collect from an applicant some additional data. It will be nice to include in any workflow an activity to do this. This activity should be:

- assigned to the applicant

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- out of the proposed order
- followed by the secretaries' or moderator's activity

This activity should contain an electronic form that allows at least collect one or more files, and writing down a textual note. The directions for the applicant can be passed using the Notes Submit feature.



Shared activities

Sometimes, the set of activities may suit more than one workflow. It is possible to use the URL of these activities in more than one workflow parameter. But, be careful!

Administrate Authorities and Users ▾ Processes ▾ Configurations ▾ Import ▾ System settings ▾ Exit

Processes

	Name	Additional information
<input type="checkbox"/>	De-registration	
<input type="checkbox"/>	Guest	First time applications
<input checked="" type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

Host applications

Save Remove Cancel || Validate Workflows

Name
Importer Inspection

Additional information
Scheduled inspection of importer's facility

URL
application.importer.inspection

Application URL
application.common.inspection

Data Configuration URL

Figure 2 Shared inspection activities

Applying again

An applicant can apply again with the same application:

- After fixing a minor problem found during the application review – "Return to Applicant" feature
- After managing a reason for the application declining
- After managing a reason for the application suspending

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Anyway, the applied again application will be passed to the first step of the workflow. Nevertheless, the executor of the first step can recognize whether the application has been passed again because the full application history is available.

To avoid the execution of extra unnecessary activities, it will be a good idea to include

Old application forms

After an application is applied, the application electronic form will be stored along with the application. The changes in the application electronic form don't impact the application already submitted.

Background activity

Some events, that should be watched in the workflow may occur outside the system. For example, application fee receiving, or lab test completion. To catch these events, background activities should be configured in the workflow. Refer to the Activity Configuration electronic manual for details.

The result of background activities completion is available in the Application History.

Scheduled or concurrent run of another workflow

Sometimes another workflow should be started as an outcome of the workflow or an activity. Examples are:

- The Renewal Workflow should be scheduled in the future after the approval of the Certification Workflow
- The Inspection Workflow should run when the Pre-Inspection workflow enters in "Waiting for Inspection" activity

The scheduled workflows are managed by the "schedulers" component placed in the electronic form of any activity. The workflow will be scheduled after the approval and will not be scheduled after the decline. of Refer to the electronic help on the Administrative-Configuration-Data Configuration page.

The concurrent workflow is managed by the activity configuration. Refer to the Activity Configuration electronic manual for details.

The results of both scheduled and concurrent workflow are available in the Application History.

Configuration

Company Registration

The Company Registration workflow allows the registration of a new applicant if it is required. The goals are:

- To fulfill the local legislation if one
- To allow more than one user to work on behalf of an applicant

Application Electronic Form

This application requires the Application Electronic form. An example is below.

Administrative Authorities and Users Processes Configurations Import System settings Exit

Data Directory

applicant.data Import Add

	url	description
<input checked="" type="checkbox"/>	applicant.data	A company as an applicant

20

Variables

applicant.data

Search Add Preview Explore

row	col	Order	Variables	ext	Class	Additional information
0	0	0	prefLabel		literals	Short company name
0	0	1	contactName		literals	contact person name
0	0	3	applicant_phone		strings	Phone number in international format +1(111)111-11-11 or +1(111)1111111
0	0	4	applicant_email		strings	Contact person email in a common format like nobody.nowhere@neverland.com
0	1	0	address		heading	Street address
0	1	1	street		literals	Street address like Arlington Ave 12/34 office 2
0	1	4	cityaddress		literals	City, Province, Zip Code
0	1	5	map_location		addresses	Select a location and put it to a map
100	100	0	users		things	Company's users
100	100	1	invoice		things	

100

Figure 3 Company Registration Electronic Form Example

- prefLabel should be short, however the understandable name of a company
- Page “users” should be defined. This page should contain a “persons” component. **The first page of the person definition form should contain the mandatory field “email”**

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Administrat... Authorities and Users Processes Configurations Import System settings Exit

Data Directory

applicant.person

ImportAdd

	id	description
<input checked="" type="checkbox"/>	applicant.person	Applicant's person maybe user or not
<input type="checkbox"/>	applicant.persons	Company's users registered

20

Variables

applicant.person

SearchAddPreviewExplore

row	col	Order	Variables	ext	Class	Additional information
0	0	0	prefLabel		literals	Full name of a person
0	0	2	description		literals	Person's responsibility and any additional information
0	0	3	email		strings	Email of a person in a simple format like real.never.man@neverland.com
0	0	4	applicationResp		heading	
0	0	5	permit_appl		dictionaries	Applications to get a new permit
0	1	2	addmodification		dictionaries	Ask for a modification
0	1	3	deregistration		dictionaries	

100

Figure 4 The mandatory field "Email" allows login on behalf of a company

Application self-check Checklist

The dictionary for the application self-check checklist is mandatory

Workflow Parameters

To configure the Company Registration Workflow, select "Guest" and press Add

Administrat... Authorities and Users Processes Configurations Import System settings Exit

Processes

	Name	Additional information
<input type="checkbox"/>	De-registration	
<input checked="" type="checkbox"/>	Guest	First time applications
<input type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

4

Applications

	Name	Additional information
<input type="checkbox"/>	New Retail Pharmacy - Individually Owned	Application for New Retail Pharmacy registration, where the pharmacy is owned by up to 5 individuals.
<input type="checkbox"/>	New pharmacy cooperative	Demo and learn example for "links" component. Not real!
<input type="checkbox"/>	New Retail Pharmacy - Company Owned	Application for New Retail Pharmacy registration, where the pharmacy is owned by a company (PVT. Ltd)
<input type="checkbox"/>	New Wholesaler - Company Owned	The wholesaler is not allowed to sell directly to consumers. This is retail. Wholesalers are inspected under another set of rules - GDP - which is much more extensive than GPP inspection for pharmacies The wholesaler has facilities for storing medicines and is buying medicine from manufacturers or importing and shipping medicine to retail pharmacies. A wholesaler can either be personally owner or company owned - which require two WF's.
<input type="checkbox"/>	Production process	
<input type="checkbox"/>	Register a company	Allow register a company and users that may act on behalf of a company
<input type="checkbox"/>	Transition Retail Pharmacy - Company Owned	Renewal of existing company owned pharmacy if the pharmacy is currently registered in DAMS (The old DDA system). Transitioning from Dams to Pharmadex. Pharmacies registered in Pharmadex

AddGuideCancel

Figure 5 Select Initial Application and press Add

Fill out the form like the example below

Administrate Authorities and Users Processes Configurations Import System settings Exit

Processes

Name	Additional information
<input type="checkbox"/> De-registration	
<input checked="" type="checkbox"/> Guest	First time applications
<input type="checkbox"/> Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/> Inspections	
<input type="checkbox"/> Modification	
<input type="checkbox"/> Shutdown	Cancel the license, authorization, etc

Add Guide Cancel

Save Remove Cancel || Validate Workflows

Name

Register a company

Additional information

Allow register a company and users that may act on behalf of a company

URL

applicant.data 1

Application URL

application.register.company 2

Data Configuration URL

applicant.data 3

Checklist Dictionary URL

dictionary.applicant.checklist 4

Figure 6 Company Registration Application

1. Application Electronic Form
2. Workflow Activities
3. Application Electronic Form (same as 1)
4. The dictionary for the self-checklist

Activities

- Follow the Workflow Activity Definition online help to create an activity.
- The successful outcome of the workflow should be “COMPANY”, not “ACCEPT”
- The DECLINE outcome is mandatory

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Administrate Authorities and Users Processes Configurations Import System settings Exit

Register a company

Save Cancel Insert before Remove Export

Workflows / Verification / Authorization / Next

Guide

Name

Authorization

Additional information

Authorize a company and company users if ones

Activity URL

activity.company.authorization

Checklist Dictionary URL

dictionary.checklist.company.authorization

hidechecklist

NA

Data Configuration URL

applicant.authorization.schedulers

Address URL

Run concurrently on enter

Send email to the applicant

Yes

Executives

Roles

Search		<input type="checkbox"/> Selected only
Name	Additional information	
<input type="checkbox"/> Accountant	ROLE_ACCOUNTANT	
<input type="checkbox"/> APPLICANT	DO NOT USE THIS FOR NOW!	
<input checked="" type="checkbox"/> Approver	Responsible for approving the application. Typically is a chief or deputy chief of a department	
<input type="checkbox"/> Initiator	Responsible for formal document's checking	

Background execution

NA

Finalize

Finalize	
Name	Additional information
<input type="checkbox"/> ACCEPT	ACCEPT
<input checked="" type="checkbox"/> COMPANY	COMPANY
<input type="checkbox"/> DECLINE	DECLINE
<input type="checkbox"/> NO	NO

Figure 7 The successful outcome should be COMPANY, not ACCEPT

Additional Workflow Required

The de-registration workflow is required. It will be nice to have a Modification workflow to allow modification of the authorized users.

The Suspension, Renewal, Pre-Inspection, and Inspection workflows are possible.

Pre-inspection

The pre-inspection is an inspection asked by an applicant to ensure compliance with the standards and/or to obtain a higher grade for the business. The subjects of pre-inspection are the applicant's facilities.

Application Electronic Form

This application requires:

- Application Electronic Form to fill out the request for the inspection
- The Certification Application electronic form defines the subject of the request. The Certification Application may not be submitted yet.

An example of the Application Electronic Form is below

Administrate Authorities and Users ▾ Processes ▾ Configurations ▾ Import ▾ System settings ▾ Exit

Data Directory

pharmacy.guest.inspection Import Add

	url	description
<input checked="" type="checkbox"/>	pharmacy.guest.inspection	Business asks for an inspection

20 ▾

Variables

pharmacy.guest.inspection

Search Add Preview Explore

row	col	Order	Variables	ext	Class	Additional information
0	0	0	prefLabel		literals	
0	0	1	inspection		dictionaries	

100 ▾

Figure 8 This simplified form asked only for an inspection of some kind defined by the dictionary

Application self-check Checklist

The dictionary for the application self-check checklist is mandatory

Workflow Parameters

To configure pre-inspection workflow parameters, select “inspection” and press “Add”

Administrate Authorities and Users ▾ Processes ▾ Configurations ▾ Import ▾ System settings ▾ Exit

Add Guide Cancel

Processes

	Name	Additional information
<input type="checkbox"/>	De-registration	
<input type="checkbox"/>	Guest	First time applications
<input type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input checked="" type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

4 ▾

Inspections by query

	Name	Additional information
<input type="checkbox"/>	Pharmacy premise	Inspect the premise and documentation to increase the rating

4 ▾

Figure 9 Add new pre-inspection workflow

Add
Guide
Cancel

Processes

Name	Additional information
<input type="checkbox"/> De-registration	
<input type="checkbox"/> Guest	First time applications
<input type="checkbox"/> Host	Renew, Suspend, Amendments, Cancel
<input checked="" type="checkbox"/> Inspections	
<input type="checkbox"/> Modification	
<input type="checkbox"/> Shutdown	Cancel the license, authorization, etc

Inspections by query

Save
Remove
Cancel
||
Validate
Workflows

Name

Pharmacy premise

Additional information

Inspect the premise and documentation to increase the rating

URL

retail.site.owned.persons 1

Application URL

schedule.pharmacy.guest.inspection 2

Data Configuration URL

pharmacy.guest.inspection 3

Checklist Dictionary URL

dictionary.checklist.pharmacy.guest.inspection 4

Figure 10 The pre-inspection workflow definition

1. Certification Application Electronic Form
2. The Application activities
3. The Pre-inspection Application electronic form
4. The self-checklist

Activities

- The ACCEPT and DECLINE finalization activities are mandatory.
- The Inspection Workflow can be running concurrently or by schedule

Refer to the Workflow Activity Definition online help for details.

data.routine.inspection.next.schedule

ImportAdd

id	description
<input checked="" type="checkbox"/> data.routine.inspection.next.schedule	Next routine inspection scheduler

20

Variables

data.routine.inspection.next.schedule

SaveRemoveCancel

Publicly AvailableNoHide from an ApplicantNo

varNameinspection_schedulervarNameExt

Additional information

screenpositionrowcolord

Classschedulers

Minimal OffsetMaximal Offsetrequiredmult

Auxiliary DataURLroutine.inspection.schedulerdictUrl

auxUrlapplication.routine.inspectionreadOnlyuniqueName

Figure 11 Ask the inspection department to run the inspection

Additional Workflow Required
The Inspection Workflow is required.

Certification

The Certification Workflow intends to get a permit to do activities related to medical products and devices.

Application Electronic Form

The Application Form for the Certification Workflow is the electronic multi-page form containing data necessary to define and classify the subject of the permit. Additionally, the form may contain the payment fee data and other required legislated information, i.e., copies of documents, photos, etc.

The division of pages is very important for future modification implementation. OpenRIMS allows to modification of data at once only on one page of the Certification Application Form.

Application self-check Checklist

The dictionary for the application self-check checklist is mandatory

Workflow Parameters

To add a new Certification Workflow, select “guest” and press “Add”

Administrare Authorities and Users Processes Configurations Import System settings Exit

Add
Guide
Cancel

Processes

	Name ↓	Additional information
<input type="checkbox"/>	De-registration	
<input checked="" type="checkbox"/>	Guest	First time applications
<input type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

4

Applications

	Name ↓	Additional information
<input type="checkbox"/>	New Retail Pharmacy - Individually Owned	Application for New Retail Pharmacy registration, where the pharmacy is owned by up to 5 individuals.
<input type="checkbox"/>	New pharmacy cooperative	Demo and learn example for "links" component. Not real!
<input type="checkbox"/>	New Retail Pharmacy - Company Owned	Application for New Retail Pharmacy registration, where the pharmacy is owned by a company (PVT. Ltd)
<input type="checkbox"/>	New Wholesaler - Company Owned	The wholesaler is not allowed to sell directly to consumers. This is retail. Wholesalers are inspected under another set of rules - GDP - which is much more extensive than GPP inspection for pharmacies. The wholesaler has facilities for storing medicines and is buying medicine from manufacturers or importing and shipping medicine to retail pharmacies. A wholesaler can either be personally owner or company owned - which require two WF's.
<input type="checkbox"/>	Production process	
<input type="checkbox"/>	Register a company	Allow register a company and users that may act on behalf of a company
<input type="checkbox"/>	Transition Retail Pharmacy - Company Owned	Renewal of existing company owned pharmacy if the pharmacy is currently registered in DAMS (The old DDA system). Transitioning from Dams to Pharmadex. Pharmacies registered in Pharmadex which is ready for renewal, should check the "ToDo" where the renewal should be initiated.
<input type="checkbox"/>	Transition Retail Pharmacy - Individual Owned	Renewal of existing individual owned pharmacy, if the pharmacy is currently registered in DAMS (The old DDA system). Transitioning

Figure 12 Add new Certification Workflow

Add Guide Cancel

Processes

	Name	Additional information
<input type="checkbox"/>	De-registration	
<input checked="" type="checkbox"/>	Guest	First time applications
<input type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

≡ 4 ▾

Applications

Save Remove Cancel || Validate Workflows

Name

New Retail Pharmacy - Individually Owned

Additional information

Application for New Retail Pharmacy registration, where the pharmacy is owned by up to 5 individuals.

URL	1	
retail.site.owned.persons		✎
Application URL	2	
application.retail.site.owned.persons		✎
Data Configuration URL	3	
retail.site.owned.persons		✎
Checklist Dictionary URL	4	
dictionary.application.pharmacy.new.init		✎

Figure 13 Configuration of the Certification Application

1. Application Electronic Form
2. Workflow Activities
3. Application Electronic Form (same as 1)
4. The dictionary for the self-checklist

Activities

Follow the Workflow Activity Definition online help to create activities. The ACCEPT and DECLINE activities are required.

The “scheduler” component for Routine Renewal is required. It can be placed in any activity form.

Additional Workflow Required

For the Certification Application must be configured:

1. Renewal
2. De-registration

Suspension, Modification, Pre-inspection, and Inspection may be configured if required.

resources.manual.workflow

Routine Renewal Application.

The Routine Renewal is required for any Certificate issued using the Certification Application workflow. The Routine Renewal can be run only by schedule.

Application Electronic Form

There is no application electronic for this workflow.

Application self-check Checklist

The application self-checklist is not used

Workflow Parameters

To add a new Routine Renewal Application, select “host” and press “Add”

Administrate Authorities and Users ▾ Processes ▾ Configurations ▾ Import ▾ System settings ▾ Exit

AddGuideCancel

Processes

	Name ↓	Additional information
<input type="checkbox"/>	De-registration	
<input type="checkbox"/>	Guest	First time applications
<input checked="" type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

4

Host applications

	Name ↓	Additional information
<input type="checkbox"/>	Conducting pharmacy inspection	The conducting inspection is NRA's internal process that typically runs concurrently with another inspection regulatory process. The goal of conducting an inspection is the inspection outcome. There are two known forms of the inspection outcome • Inspection report • Concise notes (Adhikari, 2022) Additionally, there are such known methods of inspection conducting: • Document analysis • Place visits, lab tests, etc.
<input type="checkbox"/>	Disciplinary Pharmacy Inspection	The disciplinary inspection can be initiated by Moderator or Supervisor using the Monitoring feature. The conducting inspection process runs concurrently.
<input type="checkbox"/>	Importer Inspection	Scheduled inspection of importer's facility
<input type="checkbox"/>	Importer Renew	Scheduled renew of an Importer's certificate
<input type="checkbox"/>	Pharmacy Inspection	Scheduled pharmacy inspection
<input type="checkbox"/>	Pharmacy Renew	Scheduled pharmacy renew
<input type="checkbox"/>	Renew a company	Is this company alive and the representative is valid
<input type="checkbox"/>	Routine Inspection	The first routine inspection is usually scheduled by the permit approval process. The following routine inspection will be scheduled by the previous routine inspection process. Following the Good Practices (Council) the scheduled interval may be assigned by the inspection result. The conducting inspection process runs concurrently.
<input type="checkbox"/>	Wholesaler inspection	Scheduled inspection of wholesaler facility
<input type="checkbox"/>	Wholesaler Renew	Scheduled renew of a wholesaler's certificate

4

Figure 14 Add a Routine Renewal Application

Add Guide Cancel

Processes

	Name ↓	Additional information
<input type="checkbox"/>	De-registration	
<input type="checkbox"/>	Guest	First time applications
<input checked="" type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

≡ 4 ▾

Host applications

Save Remove Cancel || Validate Workflows

Name

Additional information

URL

application.importer.renew
1

Application URL

application.importer.renew
2

Data Configuration URL

Figure 15 Configuration of Routine Renewal

1. Workflow Activities Configuration
2. Workflow Activities Configuration (same as 1)

Activities

It will be a good idea to make the first activity processed by an applicant. The APPROVE and DECLINE activities are mandatory. The APPROVE activity should contain the “schedulers” component to run this application again, after a defined interval. The behavior of DECLINE activity depends on the procedure. For example, it is possible to configure this activity by running the appropriate “Suspension” workflow.

Additional Workflow Required

The “Suspension” workflow may be defined.

resources.manual.workflow

Routine Inspection

The Routine Inspection workflow is internal for the Regulatory Authority. This workflow manages collaboration between the Registration Department and the Inspection Department. Also, known practices when the partner organization is hired to conduct an inspection.

OpenRIMS does not allow initiating the Routine Inspection by an applicant.

Application Electronic Form

There is no application electronic form for this workflow.

Application self-check Checklist

The application self-checklist is not used

Workflow Parameters

To add a new Routine Inspection Workflow, select “host”, and press “Add”

Administrate Authorities and Users Processes Configurations Import System settings Exit

The screenshot shows the OpenRIMS interface with the 'Processes' and 'Host applications' panels. The 'Processes' panel has a table with the following data:

	Name	Additional information
<input type="checkbox"/>	De-registration	
<input type="checkbox"/>	Guest	First time applications
<input checked="" type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

The 'Host applications' panel has a table with the following data:

	Name	Additional information
<input type="checkbox"/>	Conducting pharmacy inspection	The conducting inspection is NRA's internal process that typically runs concurrently with another inspection regulatory process. The goal of conducting an inspection is the inspection outcome. There are two known forms of the inspection outcome • Inspection report • Concise notes (Adhikari, 2022) Additionally, there are such known methods of inspection conducting: • Document analysis • Place visits, lab tests, etc.
<input type="checkbox"/>	Disciplinary Pharmacy Inspection	The disciplinary inspection can be initiated by Moderator or Supervisor using the Monitoring feature. The conducting inspection process runs concurrently.
<input type="checkbox"/>	Importer Inspection	Scheduled inspection of importer's facility
<input type="checkbox"/>	Importer Renew	Scheduled renewal of an Importer's certificate
<input type="checkbox"/>	Pharmacy Inspection	Scheduled pharmacy inspection
<input type="checkbox"/>	Pharmacy Renew	Scheduled pharmacy renewal
<input type="checkbox"/>	Renew a company	Is this company alive and the representative is valid
<input type="checkbox"/>	Routine Inspection	The first routine inspection is usually scheduled by the permit approval process. The following routine inspection will be scheduled by the previous routine inspection process. Following the Good Practices (Council) the scheduled interval may be assigned by the inspection result. The conducting inspection process runs concurrently.
<input type="checkbox"/>	Wholesaler inspection	Scheduled inspection of wholesaler facility
<input type="checkbox"/>	Wholesaler Renew	Scheduled renewal of a wholesaler's certificate

Figure 16 Add new Routine Inspection workflow

Activities

The APPROVE and DECLINE activities are mandatory. The APPROVE or any other activity may contain a “schedulers” component to schedule the workflow.

Additional Workflow Required

There are no additional workflows required.

Suspension

The Suspension Workflow is an internal Regulatory Authority workflow. The goal is to suspend a certificate. The application with the suspended certificate returns to the applicant. When the applicant manages the reason, it can send the application for approval again.

Application Electronic Form

There is no application electronic form for this workflow.

Application self-check Checklist

The application self-checklist is not used

Workflow Parameters

To add a new Suspension Workflow, select “Shutdown”, and press “Add”

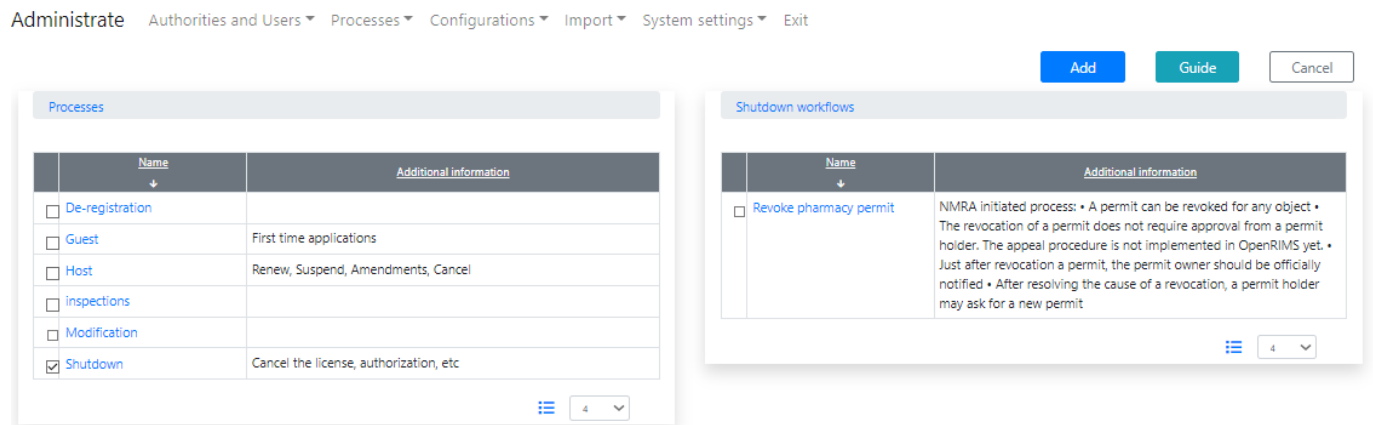


Figure 17 Add new Suspension Workflow

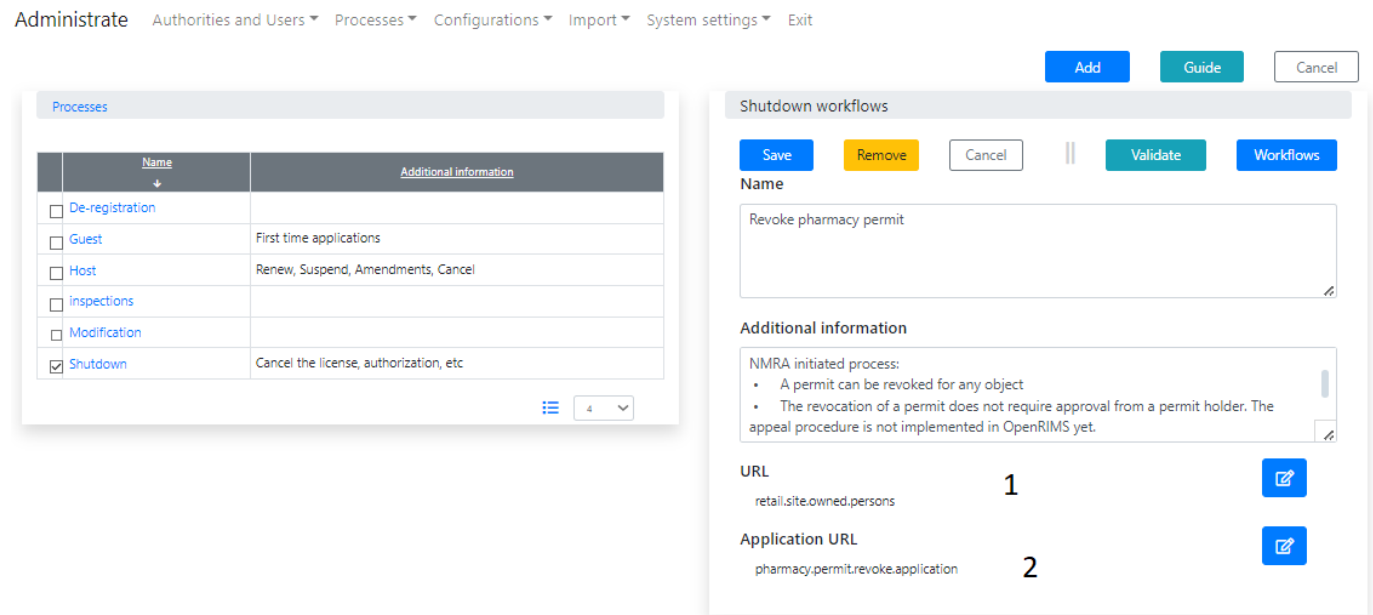


Figure 18 The configuration of the Suspension workflow

1. Application Electronic Form
2. Workflow Activities

resources.manual.workflow

Activities

The APPROVE and DECLINE activities are mandatory.

Additional Workflow Required

There are no additional workflows required.

Modification

The Modification Workflow allows making the minor application data modification in a way controlled by the Regulatory Authority. A modification may be performed at once only for information placed on one page of the Certification Application Electronic Form. The Modification Workflow can be applied only for permits with valid certificates.

The modification can be initiated only by the applicant.

Application Electronic Form

For modification application should be defined as an electronic form that contains at least two pages:

1. The first page should contain a read-only “prefLabel” text field, and, optionally, a register to assign the application number and other components such as document uploaders, classifiers, etc.
2. The second page should contain only data to modify

The extra pages, i.e., document, payment data, etc., are allowed after the second page.

Administrate Authorities and Users Processes Configurations Import System settings Exit

Data Directory

modification.pharmacy.name

Import Add

row	col	Order	Variables	ext	Class	Additional information
0	0	0	register		registers	
0	1	0	prefLabel		literals	
100	100	0	pharmacy_name		things	modify pharmacy name
100	100	1	documents		things	
100	100	2	payment		things	
100	100	3	schedule8		things	

20

Variables

modification.pharmacy.name

Search

Add Preview Explore

row	col	Order	Variables	ext	Class	Additional information
0	0	0	register		registers	
0	1	0	prefLabel		literals	
100	100	0	pharmacy_name		things	modify pharmacy name
100	100	1	documents		things	
100	100	2	payment		things	
100	100	3	schedule8		things	

100

Figure 19 The modification application electronic form

The second page of the form above should be designed specially for the modification. This page should contain fields with the same names and classes as a subset of fields on some pages of the Certification Application Electronic Form.

Modification Application page

pharmacy.name.pattern

Search

Add

Preview

Explore

row	col	Order	Variables	ext	Class	Additional information
0	0	0	prefLabel		literals	Name of the pharmacy in English. Word "pharmacy" is mandatory in the name
0	0	1	name_nepali		strings	Pharmacy name in Nepali

Certification Application page

pharmacy.site

Search

Add

Preview

Explore

row	col	Order	Variables	ext	Class	Additional information
0	0	0	rsitedetail		heading	
0	0	1	prefLabel		literals	Enter name of pharmacy in English. Should include the word "Pharmacy" both in the nepali and English name.
0	0	2	name_nepali		strings	Enter name of pharmacy in Nepali.
0	0	3	description		literals	Some additional information to a pharmacy owner consideration

The page of the Certification Application may be any, including pages in “persons” components.

Application self-check Checklist

The dictionary contains the self-check list is mandatory.

Workflow Parameters

To add new Modification Workflow parameters, select “Modifications” and press “Add”

Administrat **Processes** Authorities and Users Configurations Import System settings Exit

Add
Guide
Cancel

Processes

Name	Additional information
<input type="checkbox"/> De-registration	
<input type="checkbox"/> Guest	First time applications
<input type="checkbox"/> Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/> inspections	
<input checked="" type="checkbox"/> Modification	
<input type="checkbox"/> Shutdown	Cancel the license, authorization, etc

Modifications

☐ Selected only

Name	Additional information
<input type="checkbox"/> Owner	Add a new owner or remove an existing owner. Note that if the pharmacy is changing owner, you need to add the new first, then delete the old owner after
<input type="checkbox"/> Pharmacist	Add a new or remove an existing pharmacist. Note that if the pharmacy is changing pharmacist, you need to add the new first, then delete the old pharmacist after
<input type="checkbox"/> Pharmacist Qualification	Changes in Pharmacist membership of NPC or his/her qualification
<input type="checkbox"/> Pharmacy Address	Please note that if the pharmacy moves to another district, you need to check if the name of the pharmacy is still valid in the new district.

Figure 20 Add new Modification Workflow

Administrat **Processes** Authorities and Users Configurations Import System settings Exit

Add
Guide
Cancel

Processes

Name	Additional information
<input type="checkbox"/> De-registration	
<input type="checkbox"/> Guest	First time applications
<input type="checkbox"/> Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/> inspections	
<input checked="" type="checkbox"/> Modification	
<input type="checkbox"/> Shutdown	Cancel the license, authorization, etc

Modifications

Save
Remove
Cancel
Validate
Workflows

Name

Pharmacy name

Additional information

Change English and Nepali name of the pharmacy.
 Please make sure to check if the new name is allowed in the district.

URL

pharmacy.name.pattern	1	
-----------------------	---	--

Application URL

application.modification	2	
--------------------------	---	--

Data Configuration URL

modification.pharmacy.name	3	
----------------------------	---	--

Checklist Dictionary URL

dictionary.checklist.pharmacy.name.modify	4	
-------------------------------------------	---	--

Figure 21 The configuration of the Modification Application

resources.manual.workflow

1. The URL of the second page in the Modification Application Form
2. Workflow Activities
3. Modification Application Form
4. The dictionary contains the self-checklist

Activities

The APPROVE and DECLINE activities are mandatory. **The OpenRIMS implements the modification just before entering to APPROVE activity.**

Additional Workflow Required

There are no additional workflows required.

resources.manual.workflow

De-Registration

The De-Registration Workflow intends to permanently de-register the certificate. The modification can be initiated by the applicant.

Application Electronic Form

A de-registration Application should be defined as an electronic form. The first page should contain the read-only field “prefLabel”.

Administrate Authorities and Users Processes Configurations Import System settings Exit

Data Directory

retail.site.owned.persons.deregistration Import Add

	url	description
<input checked="" type="checkbox"/>	retail.site.owned.persons.deregistration	de-registration person owned pharmacy
<input type="checkbox"/>	retail.site.owned.persons.deregistration.documents	Documents to download for person owned retail pharmacy de-registration

20

Variables

retail.site.owned.persons.deregistration

Search Add Preview Explore

row	col	Order	Variables	ext	Class	Additional information
0	0	1	register		registers	
0	0	2	prefLabel		literals	
0	0	4	footer		heading	
0	1	0	documents		documents	

100

Figure 22 The De-Registration electronic form

Application self-check Checklist

The dictionary contains the self-check list is mandatory.

Workflow Parameters

To add a new De-Registration Workflow, select De-registration and press Add.

Administrate Authorities and Users Processes Configurations Import System settings Exit

Processes

	Name	Additional information
<input checked="" type="checkbox"/>	De-registration	
<input type="checkbox"/>	Guest	First time applications
<input type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

4

Add Guide Cancel

De-registration

	Name	Additional information
<input type="checkbox"/>	De-register retail pharmacy owned by a person	
<input type="checkbox"/>	De-register retail pharmacy owned by the company	
<input type="checkbox"/>	Deregister cooperative	

4

Figure 23 Add new De-Registration Workflow

Add Guide Cancel

Processes

	Name	Additional information
<input checked="" type="checkbox"/>	De-registration	
<input type="checkbox"/>	Guest	First time applications
<input type="checkbox"/>	Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/>	Inspections	
<input type="checkbox"/>	Modification	
<input type="checkbox"/>	Shutdown	Cancel the license, authorization, etc

De-registration

Save
Remove
Cancel
||
Validate
Workflows

Name

De-register retail pharmacy owned by a person

Additional information

URL

retail.site.owned.persons 1

Application URL

application.deregistration 2

Data Configuration URL

retail.site.owned.persons.deregistration 3

Checklist Dictionary URL

dictionary.checklist.retail.site.owned.persons.deregistration 4

Figure 24 The configuration of the De-Registration Workflow

1. The URL of the Certification Application electronic form
2. Workflow Activities
3. The De-Registration Application electronic form
4. The dictionary contains the self-checklist

Activities

The APPROVE and DECLINE activities are mandatory.

Additional Workflow Required

There are no additional workflows required.

Validation – manage all from one place

The definition of a workflow should be defined as:

1. Parameters described above
2. Data Forms
3. Resources
4. Dictionaries
5. Activity definitions

To allow manage these all from one place, the validation feature had been introduced. Currently, this feature is under development, however some functions are available

Select the parameters of a workflow and press “Validate”

Administrative Authorities and Users Processes Configurations Import System settings Exit

Processes

Name	Additional Information
<input type="checkbox"/> De-registration	
<input checked="" type="checkbox"/> Guest	First time applications
<input type="checkbox"/> Host	Renew, Suspend, Amendments, Cancel
<input type="checkbox"/> Inspections	
<input type="checkbox"/> Modification	
<input type="checkbox"/> Shutdown	Cancel the license, authorization, etc

Applications

Save Remove Cancel || **Validate** Workflows

Name

New Retail Pharmacy - Individually Owned

Additional information

Application for New Retail Pharmacy registration, where the pharmacy is owned by up to 5 individuals.

URL

retail.site.owned.persons

Application URL

application.retail.site.owned.persons

Data Configuration URL

retail.site.owned.persons

Checklist Dictionary URL

dictionary.application.pharmacy.new.init

Figure 25 Starting the validation feature

Reload Help Close

▼Electronic Forms 1

URL	
extern.links	✓
owner.details	✓
person.qualification	✓
pharmacist.details	✓
pharmacist.employee.agreements	✓
pharmacy.name.check	✓
pharmacy.retail.site.solution	✓
pharmacy.site.certificate	✓
pharmacy.site.inspection.reports	✓
pharmacy.site.payment	✓

Reload Help Close

Add
Preview
Explore

row ↓	col ↓	Order ↓	Variables	ext	Class	Additional information
0	0	0	fathername		literals	
0	0	1	mothername		literals	
0	0	3	grandfathername		literals	

2
100

2

1. The green color means OK. The electronic forms sections are expanded.
2. The full-fledged electronic form editor
3. The red color means something is wrong

Only the Supervisor User can import a workflow. The feature can be found on “Administrative-Import-Import workflow”. To import a workflow the Supervisor User should use the feature for the following tasks:

- After the successful importing, the post-importing tasks should be completed:

- The details can be found in the corresponding electronic help

serverurl

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