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1. Login to the Reporting Tool for customers of the RvA.

An assessment by the RvA at your organisation is scheduled soon. This assessment will be reported via the RvA's Reporting Tool.

Use this URL to log in: <https://prisma.rva.nl/login>

If this is the first time reporting through the Reporting Tool, you will receive a link from the Reporting Tool via email. This link allows you to create your own username and password. The link is sent from no-reply@prisma.rva.nl.

The link is valid for three days. Should it expire, you can re-generate the link yourself by clicking "Forgot Password" on the login page or ask your PCA to send you a new one.

The login process uses two-factor authentication (2FA). First, you enter your username and password and click the "Login" button. You will then receive in your mail the two-factor authentication link, which opens the Reporting Tool immediately. No additional software is required for this 2FA.

2. Overview of the Reporting Tool.

After the review, you have received an email that the LA has generated a Non-conformity-report and/or findings report and has become viewable to you in the Reporting Tool.
To read and respond to reports and NCs, log into the Reporting Tool.

During the review, the subproject has *New* or *In-progress* status. After your research is administratively completed, the subproject will have the *Completed* status. This can be found under the subprojects 'Completed' button.

My tasks

Under "**My Tasks**" you can find tasks that specifically have your name attached to them, and an action is expected from you.

My subprojects

Under '**My subprojects**', ongoing subprojects (reviews) are visible. After clicking open a subproject, four topics per tab are distinguished: 'findings', 'nonconformities', 'documents' and 'reports'.

3. User Management

In July 2023, the RvA launched version 3.0 of the Reporting Tool. As of this version, it is possible for customer representatives, who have been given the role "customer administrator" after this update, to delegate tasks to colleagues within their own organisation. From now on, the customer administrator himself bears the responsibility to create, modify and delete persons/accounts within the organisation.

3.1 Creating other client-administrators and client-users

Users are not attached to a subproject, but to your organisation. You can therefore create, edit and delete users at any time and independently of the assessment cycle.

- In the left menu, click on the "**Users**" button. Here you will see an overview of the users within the organisation listed at the top of the page.
- Create a new user using the top right **'+ Invite User'** button.
- Enter the name, email address and language. It is also possible to choose between client-administrator and client-user.
- Click on "**Save**". The person will receive an invitation in his/her email to create an account in the Reporting Tool.

Do I make my colleague client-administrator or client-user?

You are free to distribute roles among yourselves. Client-users have fewer privileges than client-administrators.

Customer administrators can:

- > invite new users.
- > resend invitations (*Users -> Invitations -> envelope at the end of the line*).
- > Remove other client-administrators and client-users (except the client-administrator with the active default checkmark).
- > Modify the administrator/user role of colleagues.
- > Activate the default checkbox in client-administrators.
- > Assign the NCs to 'accountable' and 'executive' persons and modify them later if necessary within the Non-conformities page of a subproject.
- > 'accountable' and/or 'executive' of NCs.
- > submit a response to an NC directly to the RvA.
- > Upload documents and delete documents from all users.

Customer users:

- > have access to the User Overview and the findings, non-conformities, documents and reports of all subprojects their organisation is working on.
- > can upload documents and delete their own.
- > cannot be "accountable" within the NC, only "executive".
- > can view all NCs, but can only respond to NCs assigned to them by a customer administrator (see Section 4.1 "Assigning tasks to colleagues within your organisation").
- > Can NOT send responses directly to the RvA; the response always goes to the client-administrator who assigned them to the NC.

3.2 Meaning and application of the default check mark

For one customer administrator within your organisation the default check mark is active. The person with the default check mark on will initially be assigned the NCs by the RvA. A user account with an active check mark cannot be deleted.

3.3 User limit

Currently, you (in the role Customer administrator) can create unlimited accounts for your organisation. You also have the ability to delete accounts. We ask that you delete accounts when they are no longer needed. Deleting an account does not affect the nonconformities edited with this account. The RvA will continue to monitor this periodically.

We will evaluate account usage across all customers one year after the Reporting Tool version 3.0 is deployed and reserve the right to charge from the third user account onwards from that time.


4. Allocation and handling of NCs.

Customer administrators have editing rights for each NC by default. Customer users have read-only rights. To give a customer user editing rights, a customer administrator must assign them to one or more NCs.

4.1 Assigning tasks to colleagues by customer administrator

To assign tasks to colleagues, the customer administrator goes to 'My subprojects' and selects the subproject. Click on the 'Non-conformities' tab for the overview of NCs.

Under the non-conformities tab, the client-administrator has a delegate button:

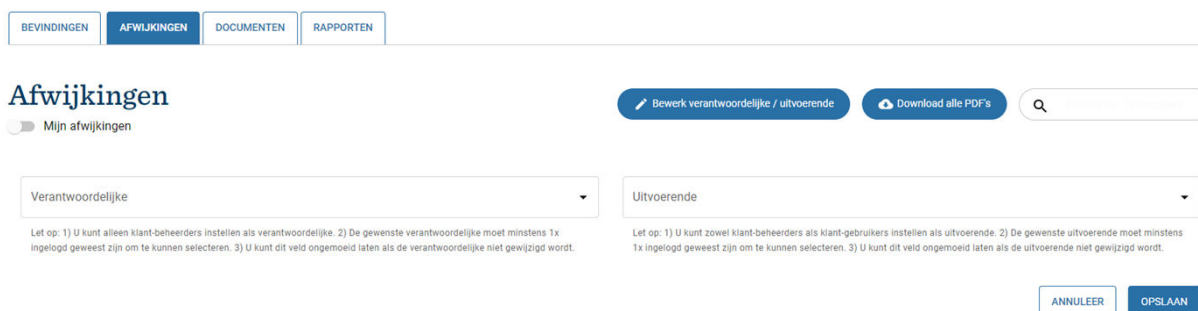
 Bewerk verantwoordelijke / uitvoerende

Select one or more NCs to assign and choose from the two dropdown menus who may become "accountable" and "executive".

An **accountable** is a customer-administrator who may send responses to NCs to the RvA on behalf of the organisation. You can only set customer administrators as accountable.

An **executive** is a customer-administrator or customer-user who may formulate a response for the relevant NC(s).

- An **executive** client-administrator may submit the response directly to the RvA.
- An **executive** customer-user may send the response only to the NC accountable.



BEVINDINGEN AFWIJINGEN DOCUMENTEN RAPPORTEN

Afwijkingen

Mijn afwijkingen

Bewerk verantwoordelijke / uitvoerende Download alle PDF's

Verantwoordelijke Uitvoerende

Let op: 1) U kunt alleen klant-beheerders instellen als verantwoordelijke. 2) De gewenste verantwoordelijke moet minstens 1x ingelogd geweest zijn om te kunnen selecteren. 3) U kunt dit veld ongemoeid laten als de verantwoordelijke niet gewijzigd wordt.

Let op: 1) U kunt zowel klant-beheerders als klant-gebruikers instellen als uitvoerende. 2) De gewenste uitvoerende moet minstens 1x ingelogd geweest zijn om te kunnen selecteren. 3) U kunt dit veld ongemoeid laten als de uitvoerende niet gewijzigd wordt.

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Click **"Save"**. The selected people can be modified again at any time.

The substitute or substitutes will receive a notification in their email that the task has been assigned to them.

Note that newly created users must first set up their username and password using the invitation in the email before they can be connected to an NC.

4.2 Vacation and sick leave replacement

Is your colleague currently on leave, or has a colleague left your organisation? You now have control over who takes over specific tasks from them. The person in question does not have to take any action. It is recommended to have at least **two** customer administrators in your user overview. Customer administrators, unlike customer users, have rights to modify the division of tasks for NCs. Should one customer-administrator not be available or leave, the other customer-administrator can easily take over the delegation process.

4.3 The Role of Executive

After selecting a colleague, they will receive an email that this task is ready for them in the Reporting Tool.

- > If the colleague has the role of client-administrator, he/she can formulate a response and send it directly to the CoA.
- > If the colleague has the role of customer-user, he/she sends the response to the person accountable for the NC. This person will receive a notification by e-mail. The person accountable will check the response, possibly adjust it, and if approved, send it to the RvA.
- > If the accountable party does not agree with the executive's response, he/she can return the task to the executive. The sender will then again receive an email notification and editing rights for the NC. After editing the response, the performer can resubmit the response to the accountable party. These draft response(s) cannot be viewed by RvA assessors or PCA's, only by RvA functional administrators. This in case it is necessary to provide assistance if problems arise.

At any time, customer administrators can modify accountable and executive persons using the blue delegate button.

4.4 Answering NCs

An overview of the NCs can be found under the 'Nonconformities' tab. Use the '**My Non-conformities**' slider under the 'Non-conformities' heading to sort by the NCs to which your name is associated and for which you currently have a task open.

If there are open NCs, you can download them separately using the '+ **Download PDFs**' button. You can use this to distribute the NCs within your organisation, in case you do not want to use the delegation option within the Reporting Tool. When all NCs are closed, the button is no longer visible and the NCs can no longer be downloaded.

Click on the 'eye' on the right side of an NC to open it. On the left side you will find the necessary information and explanation about the written out non-conformity. On the right side you can formulate a response.

A special character may be entered when entering a finding or non-conformity. In that case, make use of the special characters supported in the tool. You can search for a supported character in the text fields for this purpose.

Subproject details

Relatie: Klant XYZ | Slotbespreking: 08-04-2022 | Taal:

← TERUG NAAR AFWIJKINGEN

ID: NCB-01
Eigenaar: Connie van Westing

Aanmaken NC
 Goedkeuren NC
 Beantwoorden NC
 Beoordelen reactie klant
 Goedkeuren reactie assessor

Subspecialisme(s)

SPECIALISME GROEPEN	SPECIALISMEN	SUBSPECIALISMEN
Biometrie	Devarmetrie	Bondichtheidsmeting via Dual Energy X-ray
Klinische Farmacie	Enkel-arm index	absorptiemetrie [technische uitvoering]
		Doppler techniek [technische uitvoering]

Betreffende normparagraaf

ISO 15189: 2012

4.4.2 Beoordelen dienstverlenings overeenkomsten

Aanmaken NC

Soort onderzoek	Bezoek aan laboratorium
Eisen	Normen
Locatie(s)	Den-Bosch
Auditee (Naam, functie)	Mevr. de Boer (inkoper)
Ingezonden registraties en documenten	Inkoopdossier ABC
Waarnemingen	Inkoopdossier is incompleet

Beantwoording afwijking

De eerste beantwoording door u op de vastgestelde afwijking dient ten minste in te gaan op de Oorzaak, Omvang en Herstel en corrigerende maatregelen. Uitleg over wat er precies verwacht wordt in de beantwoording is onder de informatie button "I" per rubriek (oorzaak, omvang en herstel) veeergegeven. Desgewenst kunnen documenten als bijlagen worden toegevoegd.

Oorzaken *

Oorzaak A

Omvang, impact *

Omvang B

Impact C

The RvA uses a system of responding to 4 questions. See below one another the entry fields:

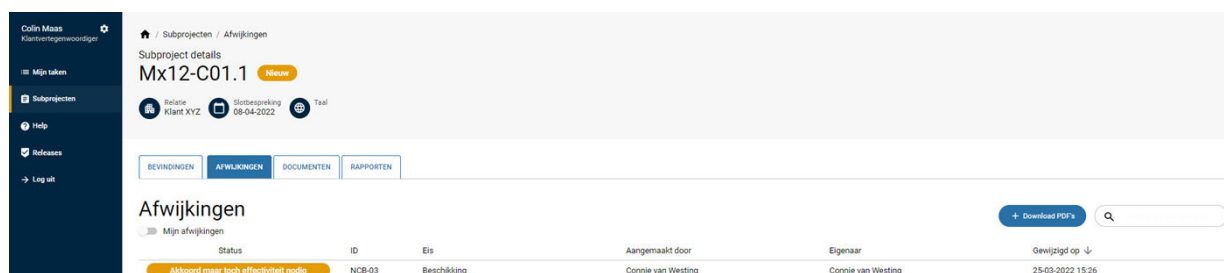
- Causes
- Size, impact
- Remedial and corrective actions
- Explanation of effectiveness of measures taken

Basically, you only need to respond to the first 3 questions in the first round. You may be asked later if you wish to respond to the 4th question. For the exact deadlines and information on which questions need to be answered, please consult the Policy Rule *Nonconformity and Corrective Action* (BR004). This can be found on the RvA website.

You can hover your mouse over the information "i-tips" (tooltips) and additional information will appear. At the very bottom of the input fields you can add any supporting files. After a file is saved, you can also delete it using the red trash can.

4.5 Resubmission of response to NC

If the Technical assessor (TA) and/or Lead assessor (LA) partially agree with the delivered response, or in case the TA and/or LA do agree with the 3 delivered responses, but still require a response to the 4^e question (effectiveness of measure taken), you will receive a new task in the Reporting Tool and your email.



On the left you will again see the nonconformity with an additional response from the Technical assessor or Lead assessor.

Beoordelen reactie klant

Ronde 1

Oorzaak	Akkoord
Omvang en impact	Akkoord
Genomen Correcties & corrigerende acties	Akkoord
Bewijs effectiviteit genomen acties	Niet akkoord
Toelichting op beoordeling afwijking	Extra toelichting benodigd.
Conclusie	Aanvullende reactie nodig
Uiterlijke reactie klant (opnieuw indienen)	donderdag 29 september 2022

To the right, please enter your response for the second round CAR.

Beantwoording afwijking

De eerste beantwoording door u op de vastgestelde afwijking dient ten minste in te gaan op de Oorzaak, Omvang en Herstel en corrigerende maatregelen. Uitleg over wat er precies verwacht wordt in de beantwoording is onder de informatie button "i" per rubriek (oorzaak, omvang en herstel) weergegeven. Desgewenst kunnen documenten als bijlagen worden toegevoegd.

Oorzaken *

↶ ↷ **B** *I* U ☰ Ω PDF ✎

Omvang, impact *

↶ ↷ **B** *I* U ☰ Ω PDF ✎

Fill in all fields. For the statuses 'update by customer' or 'demonstrate effectiveness', fill in the fields that (do) agree as well (all fields must be filled in mandatory). Enter 'see round 1' here.

5. Uploading and downloading files

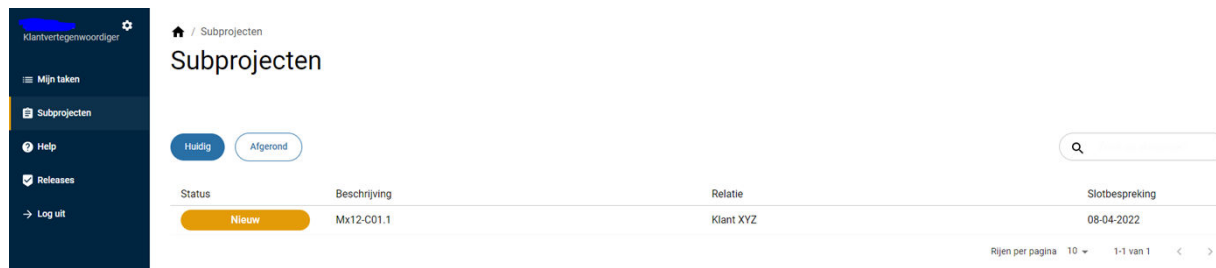
Four weeks prior to an assessment, the assessors start preparing for the assessment.

You are requested to upload documentation in accordance with Policy BR005 into the Reporting Tool at this time. In doing so, it is important that the folder structure and numbering match the format in Appendix 1 of BR005.

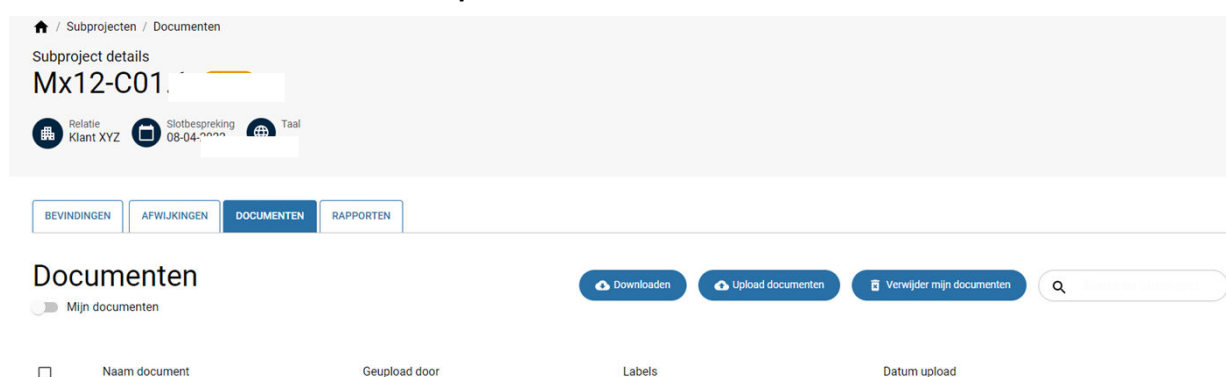
Both client-administrators and client-users can upload documents. Customer administrators can delete documents of all users, customer users can only delete documents uploaded by themselves.

Uploading unzipped folders is not possible. Please save these folders first as one ZIP file and upload this zip file in the Reporting Tool.

In the left column, go to "Subprojects," click on the line of the corresponding subproject.



Go to the 'Documents' tab. Click on 'Upload documents'.



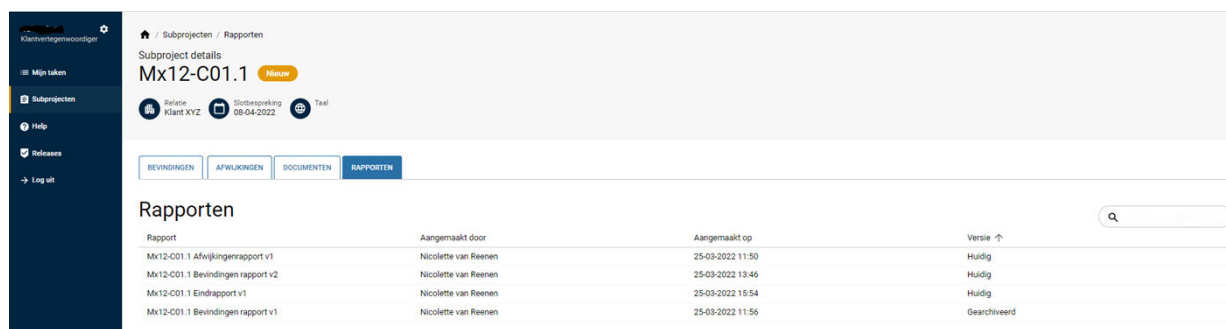
You can upload the file by dragging and dropping or by clicking on the upload area. This will take you to your own files. Select the label 'Documents (ZIP, in accordance with folder structure BR005)'. Please upload any additional documents with the appropriate label attached. See appendix 1 for an overview of all possible labels.

The following file types are supported and can be uploaded:

- Office documents: .docx, .xlsx, .pptx, .pdf
- Outlook items
- Photos: .png, .img, jpeg and .jpg
- Scanned documents: .tiff, .jpg, .pdf
- Zipfiles

6. Nonconformity report, findings report, final report.

Under the 'Reports' tab you will find all the reports you can download.



Subprojects completed with the previous client-administrators and users are not visible to the new client-administrators and users. The Reporting Tool is not intended to be a filing system. The new client-administrators and users will receive the final report transferred from the previous client-administrators and users or can request it from the PCA.

7. Changes compared to previous version

The entire document has been adjusted due to the release of the Reporting Tool 3.0, the main changes are:

- The customer role has been changed from Customer Representative to Customer Administrator and Customer User.
- The overview of the Reporting Tool has been adjusted (Chapter 2).
- Chapter 3 'User Management' (Customer Administrator and Customer User) is completely new.
- Chapter 4 'Assignment and handling of NCs' is completely new.
- The chapter division has been completely adjusted.

Appendix 1 - Labels to documents

- Documents (ZIP, conforming to folder structure BR005)
- Excerpt from the Chamber of Commerce
- KHB and general management system procedures
- Work rules and procedures
- Cross reference standards requirements and quality system
- Adapted Report Part A
- Documentation in accordance with SAP
- Additional documentation
- Internal audit reports and audit planning
- Management review
- Certification/inspection scheme
- Audit plan, report
- Inspection order, forms
- Qualifications auditor(s)/inspector(s).
- Operations list (flexible scope)
- Other documents in accordance with BR005
- Source scope