CLIA Intake

The SA and RO need to coordinate closely to assure clear communication about complaint investigations of CLIA labs that require RO approval. The RO Approval tab on the ACTS Intake screen is the CLIA equivalent of the Deemed tab for deemed providers. It replicates the portions of the CMS-2802A form used to authorize a complaint investigation and to identify those areas of the lab's operations that are to be investigated. It includes additional information (such as Priority) and provides a common area where states and regions can track the progress of the CLIA complaint process.

The RO Approval tab is enabled or disabled based on the value of the Certificate at Time of Alleged Event field on the Intake tab and the Certificate Type field on the RO Approval tab. When the RO Approval tab is enabled, the SA must obtain approval from the RO to conduct an investigation.

The RO Approval tab is enabled if one of the following is selected for Certificate at Time of Alleged Event on the Intake tab:

- Waiver
- Accreditation
- Registration (Accreditation)
- PPMP
- No Current Active Certificate

For other intakes on CLIA labs that do not require an RO approval process prior to an investigation, the RO Approval tab will be visible, but disabled.

A State Agency receives an allegation of noncompliance against a CLIA lab requiring RO approval to investigate.

The SA enters the intake information and requests RO authorization to conduct an investigation.

1 Create a new intake and enter basic intake information.

- Open **ACTS**.
- In My Selections, right-click **CLIA** and click **Activate**.
- Expand the node for your training letter.
- Right-click the **<A> CLIA Intake** facility, where <A> is your training letter, and click **New Intake**.

Note the name of the provider.

- On the Intake tab, for the Certificate at Time of Alleged Event field, select **Waiver**
- Verify the Intake Subtype is **A Federal COPs …**.

Note: Incidents cannot be logged for intakes on CLIA labs!

- In the Responsible Parties section, click **Add R.O**., select the RO version of yourself, and click **OK**.

You were automatically added as the S.A. Responsible Party when you created the intake.

- On the **Complainants** tab, type **Wagner** for the last name.
- Click **Find/Add.**
- Click **New.**
- Complete the fields in this window, with a first name beginning with your training letter, and click **OK.**
- For Alleged Event Date, enter **07/15/2015**
- Source: **01 Resident, Patient, Client**
- In the Response information section, for Priority select **R – Non-IJ**

Put your cursor on the gray dot to the left of the Priority checkboxes. Notice that the Hover Help is CLIA specific.

- Investigate Within: **30**
- Click **Calculate** and select **Working Days**

2 Enter Allegations

- Click the **Allegations** tab.
- Click **Add**.
- For Category, select **72 Facility Administration** … and click **OK**.

The RO Approval tab is used to communicate key information regarding the RO Approval or Disapproval process when necessary for a CLIA lab complaint.. Both SA and RO users may view or log the following information on the RO Approval tab: Certificate Type (if Certificate at Time of Alleged Event is *No Current Active Certificate)*, Priority, Received End Date and Time, and Areas to Investigate. Only RO users may Signature information.

3 Request authorization to conduct investigation

- Go to the **RO Approval** tab.
- Click the checkbox beside **Request for RO Approval**.

ACTS sets the intake Status to 2 - Pending RO Approval - if the existing Status is 1 - and sends an RO Approval action item message to the responsible RO. If the Status is already greater than 2, Status stays the same, but an action item message is sent.

If no RO responsible party is specified for the intake, the action item message is sent to every RO user in the current region.

- For Areas to Investigate, select **Testing Within Certificate Type.**

The field to the right is now enabled for entering comments. This area centralizes State Agency and Regional Office communication.

- Enter some comment text.
- Click **OK** to close the intake, and **OK** to confirm.
- Close ACTS

The RO opens the intake to approve the investigation.

4 Open the intake in ACTS-RO

- Open **ACTS-RO**.
- Make sure the ACTS Selection is set to **CLIA**.
- Go to the **Status** tab.
- Expand **2 – Pending RO Approval**.
- Expand the **CLIA Non-IJ** node.
- Right-click your intake and select **Modify Intake**.

The RO reviews the intake and approves the investigation.

5 RO Approves the intake

- Select the **RO Approval** tab.
- Enter some text in the **Comments** field.
- For RO Response, select **01 Approved**.

All fields in the Signature section are required for finalization and investigation survey upload except Comments, unless Priority is T - Non-CLIA Referral or the intake was created by RO/CO.

- For Regional Representative, enter your name.

- Click **OK** to close the intake and **OK** to confirm.
- Press **F5** to refresh your screen.

When you enter an RO Response, either Approved or Disapproved, the Status of the intake changes from 2 - Pending RO Approval to 3 - Pending Review/Assignment. If Status is already 3 or greater, it stays the same.

- On the Status tab, expand **3 – Pending Review/Assignment**.
- Expand the **CLIA Non-IJ** node.

  Your intake should be listed.
- Close ACTS-RO.

Once RO approval is received the SA can schedule the investigation and conduct the survey as for non-CLIA providers.

6 SA prints report to show intakes without scheduled surveys

- Open **ACTS**.
- Select **Reports | Intakes without Scheduled Surveys**

In the Customization View field, select **CLIA**.

- For Base time frame on, select **Received End Date.**
- Click **OK**.
- Your facility should be listed on the report.