	Standard Operating Procedure	SOP Number C-111	Revision 1
	Redzone General Use	Effective Date 05/10/24	Page Page 1 of 23
Written by/ Date K. Bunn 03/23/24	Reviewed by/ Date Vandana Shukla 03/25/24	Approved by/ Date [Signature] 05-25-24	
Title: Quality Assurance Director	Title: Document Control Supervisor	Title: VP of Quality & Regulatory Affairs	

1.0 Purpose

The purpose of this procedure is to provide instructions for general operations within Redzone.

2.0 Scope

This procedure applies to the general use of Redzone. SOPs specific to particular functions or tasks provide details for the use of Redzone as applicable.

3.0 Responsibility

- 3.1 All employees that use Redzone (i.e. have a Redzone login profile) must understand the basic Redzone principles outlined in this procedure.
- 3.2 It is the responsibility of Document Control to periodically review and provide updates to this procedure.

4.0 Definitions

- 4.1 **RZ** – Redzone; Mark Sutcliffe founded Redzone Production Systems in 2013. The company website is <https://rzsoftware.com/> and provides additional information about the product.
- 4.2 ***RZ Admin*** – When written in bold and italic font, this is the Redzone backend application used to configure the system.
- 4.3 ***Redzone*** – When written in bold and italic font, this is the Redzone frontend user application.

Standard Operating Procedure Redzone General Use	SOP No C-111	Rev 1	Page 2 of 23
---	-------------------------------	------------------------	---------------------

- 4.4 **Backend Application** – The backend application provides tools to set user permissions, define locations to use RZ, define products and associated characteristics, define shifts, define datasheets, and define triggers.
- 4.5 **Frontend Application** – The frontend application provides the interface for using the RZ Software in the production environment. It is the end user interface.
- 4.6 **Datasheet** – Unless explicitly stated otherwise, a datasheet is an RZ component of the RZ Compliance Module that is configured in *RZ Admin* and used in *Redzone* to collect data.
- 4.7 **Handwritten Signature** – Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.
- 4.8 **Digital Signature** – Digital signature means an electronic signature based upon cryptographic methods of originator authentication that is computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.
- 4.9 **Electronic Record** – Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.
- 4.10 **Electronic Signature** – Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature.
- 4.11 **cGMP** – Current Good Manufacturing Practices
- 4.12 **Sign Off** – Approval of quality checks conducted during a completed run

- 4.13 **Action Number (#)** – a unique number assigned to each data sheet. Action numbers are available at the top of the data sheet on the action screen for data sheets that are not completed and at the top of the data sheet for data sheets that are completed. The action number is also visible in the comments section next to each linked data sheet.
- 4.14 **Statistical Process Control (SPC)** – a set of statistical rules to evaluate data from a process as data is collected and indicate when adjustments are needed to maintain control of that process. SPC configuration of data sheets identifies specific numerical product characteristics (e.g. tablet or capsule weight, tablet thickness, etc.) to apply SPC rules to.

5.0 References

- 5.1 A-106, SOP, Documentation Guidelines for cGMP Records
- 5.2 QS-116-F1, Form, Electronic Signature Acknowledgement and Consent

6.0 Overview

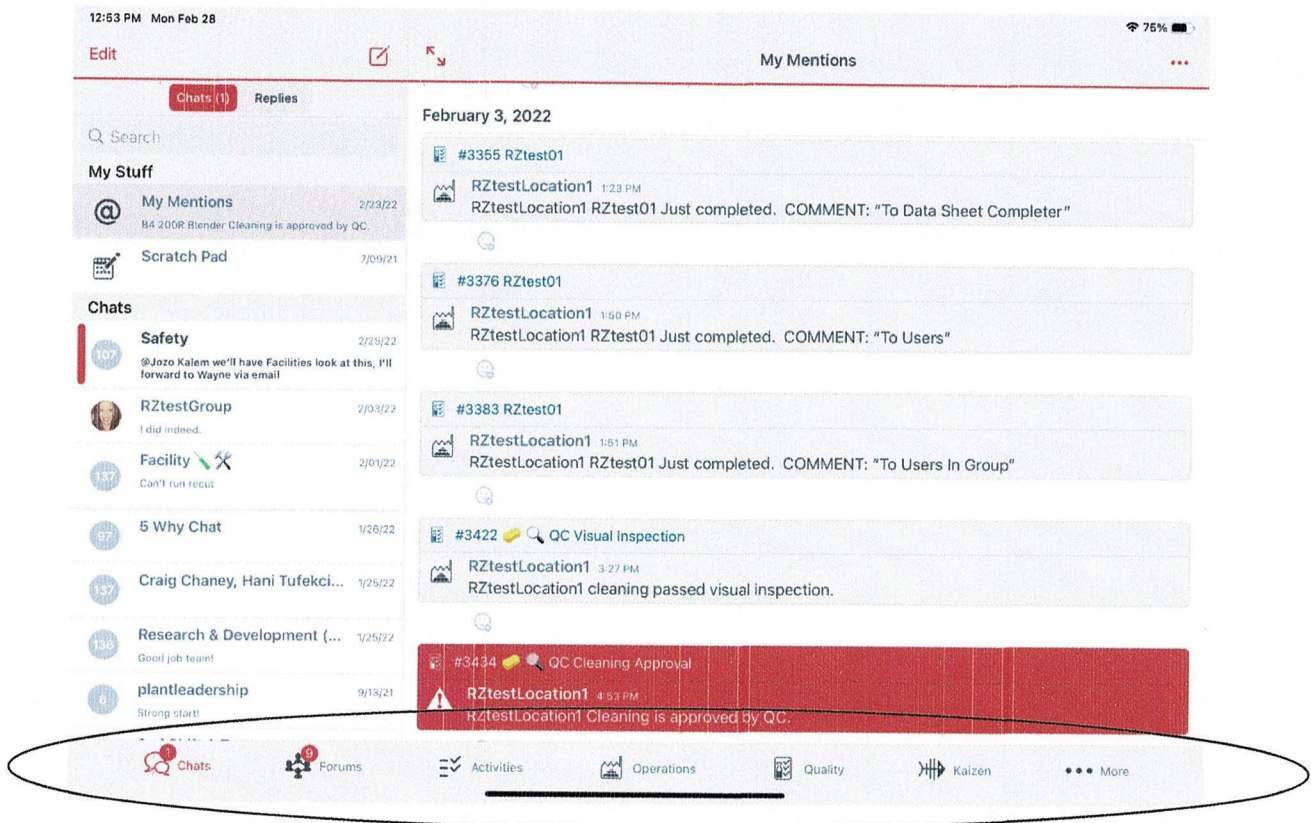
- 6.1 Ion Labs uses RZ for both non-GMP business functions as well as cGMP-regulated functions. RZ utilizes “data sheets” to collect cGMP data and electronic signatures. Ion Labs uses RZ data sheets to replace many conventional paper-based systems for logbooks, forms, and batch data. RZ is capable of automating the initiation of data sheets and is able to send out alerts based on various events, periods, or data sheet status. This automation helps ensure compliance with SOP and regulatory requirements.
- 6.2 This procedure provides general instructions for using RZ and RZ tools. Other procedures specific to a particular task or function provide detailed direction for using RZ in those activities

7.0 RZ Knowledge Base

7.1 The Knowledge Base available in the *Redzone* application and the *RZ Admin* application both accessed through the “More” tab provides detailed information about navigating within the application and provides “how to” details to perform many of the functions described by this procedure, which is not necessary to repeat here. Consult the Knowledge Base as needed.

8.0 Main Screen

8.1 The following screen shot shows the main screen of the *Redzone* application with “Chats” selected.



8.2 The main screen provides access to the key focus areas, seen across the bottom of the screen with an overview of the functionality below.

8.2.1 Chats

8.2.1.1 This area of RZ organizes communication between groups, as well as automated alerts and comments. Personnel initiate chats as needed much like texting on a phone. All forums create a chat group automatically. Admins may create new chat groups in the *RZ Admin* application.

8.2.1.2 Navigate to Chats as follows:

- Main Screen → Chats

8.2.2 Forums

8.2.2.1 The Forum is the basis for action cycles in Redzone. Use Forums to organize and monitor meetings, huddles, or kaizen events. Forum Types include Huddle, Daily, Weekly, or Custom. Open a forum by selecting the forum and then selecting “Open Forum” in the upper right corner of the screen. Begin the forum meeting by clicking the play button in the top right of the screen. Admins may create new forums in the *RZ Admin* application.

8.2.2.2 Navigate to Forums as follows:

- Main Screen → Forums

8.2.3 Activities

8.2.3.1 Activities are a key concept in driving accountability and follow up in Redzone. There are many different places that activities can be created. This ensures that users can quickly and easily create them from anywhere in the application, saving time and ensuring the information is captured and enters the action cycle.

8.2.3.2 There are four main components in Activities:

- Actions
- Issues
- Ideas
- Work Requests

8.2.3.3 All activities can be found in one central location in the Redzone app, under the Activities menu tab along the bottom of the screen. This activities dashboard will default to showing only unassigned activities and activities assigned to the logged in user. View activities in either a List view or a Board view.

8.2.3.4 Navigate to Activities as follows:

- Main Screen → Activities

8.2.4 Operations

8.2.4.1 The Operations Dashboard is key to getting information about production activity in each area and location. The dashboard updates automatically on a periodic basis. In the upper right corner of the dashboard are options to manually update the dashboard, view a list of huddles, and filter the contents displayed.

8.2.4.2 Selecting an area displays locations in that area. Selecting a location from there or directly from the main dashboard opens the dashboard for that specific area. More information is available on this dashboard by swiping left and right. From this location dashboard, there are additional opportunities to navigate to detailed information about that location by selecting from the options on the left which include the following:

- Data Center
- Settings
- Problems
- Quality
- Log

8.2.4.3 Navigate to Operations as follows:

- Main Screen → Operations

8.2.5 Quality

8.2.5.1 The quality dashboard provides an overview of all location similar to the operations dashboard; however, the information summarized on this dashboard focuses on data sheets rather than productivity metrics. Each location displays colored tiles for each completed data sheet indicating the status of the data sheet (Pass, Warn, Fail, Missed, Cancelled, or Voided). Each location displays the number of pending data sheets next to an ellipsis ●●● which if selected provides options for more detailed views as follows:

- Pending Data Sheets (a shortcut to the pending data sheets for that specific location)
- Run Quality Dashboard
- Operations Page (a shortcut to the Operations page for that location)

Note: Viewing pending data sheets from the main screen Quality dashboard will display all pending data sheets, while viewing the “Backlog Data

Sheets” from the Operations Quality Screen does not display data sheets that are not configured as “operation checks” and are instead intended for Quality to complete

8.2.5.2 Navigate to Quality as follows:

- Main Screen → Quality

8.2.6 Kaizan

8.2.6.1 The Kaizen dashboard allows the creation, tracking, and reporting of Kaizen events. This feature is currently not in use.

8.2.6.2 Navigate to Kaizan as follows:

- Main Screen → Kaizan

8.2.7 More

8.2.7.1 The “More” option on the main screen provides a number of miscellaneous functions, many of which are available through other dashboards and screens, but may present these items in a different format. The list below provides available options with the most frequently used in bold font.

- Profile – select preferred language, update use passwords and signature pins, and adjust preference settings
- Knowledge Base – provides detailed information about navigating within the application and provides “how to” details to perform many RZ functions
- Create – allows the creation of actions, issues, and ideas; you may also start a chat, quality check, production check, or audit

- Forums – lists available forums
- Locations – lists locations
- Fishbones – lists completed fishbone diagrams (this feature is currently not in use)
- My Dashboard – displays the same dashboard by selecting “Operations” at the bottom of the main screen
- Sign Off Dashboard – displays a dashboard designed to sign off runs if the user has appropriate permissions to do so
- 1 Panel View – uses filters to look at various information (e.g. OEE Trend, Availability Trend, Quality Trend, etc.) across specific areas over a specified period of time
- 2 Panel View – summarizes OEE and Problems for specific sites, areas, or locations over a specified period
- Historical Report Search – uses filters to view Shift Reports, Run Report, or Quality Reports; allows the narrowing of results to specific locations, products, periods, Run ID, or customer reference parameters
- Data Sheet History – uses filters to view data sheets; allows the narrowing of results to specific data sheet type or template name, as well as data sheets executed for specific locations, products, results, product groups, manufacturing types, assets, asset types, periods, etc.; allows for the search of specific results entered into the data sheet

- SPC Report Search – uses filters to view data sheets; allows for the narrowing of results to specific locations, products, and product characteristics; also include a period for included data

8.2.7.2 Navigate to the “More” options as follows:

- Main Screen → More

9.0 Operations Screen

9.1 Navigate to the Operations screen as follows:

9.1.1 Main Screen → Operations

9.2 Selection of the Operations tab on the Main screen displays a list of available sites, areas, and locations. The image below shows the top portion of this list.



9.3 Scrolling down on this screen allows view of individual locations. This screen provides a summary of the subject site, area, or location. Selection of a specific Site or Area provides a similar screen with locations associated for that selection. Selection of a specific location provides a more detailed Location Screen.

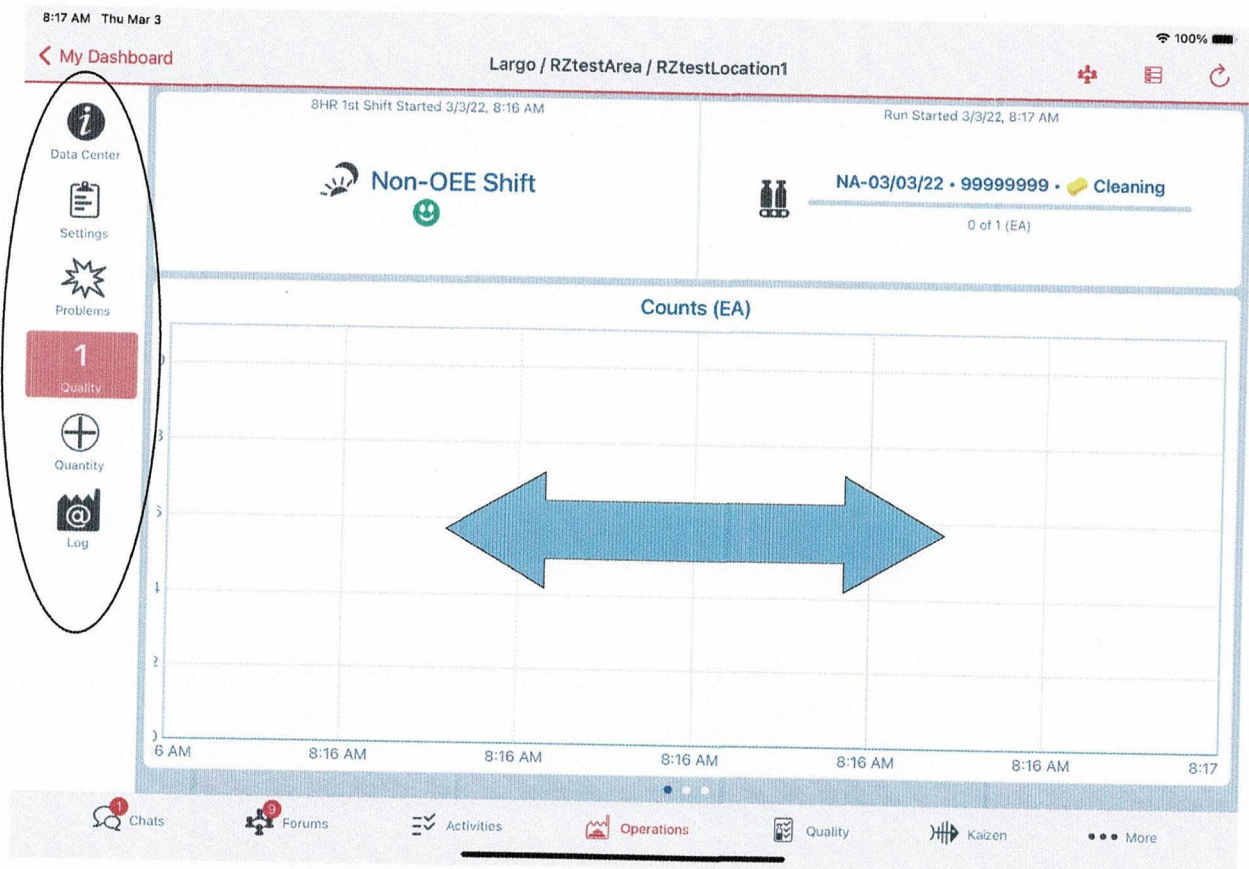
9.4 Operations Location Screen

9.4.1 Main Screen → Operations → select a specific location

9.4.2 Main Screen → Operations → select a specific area → select a specific location

9.4.3 Main Screen → Operations → select a specific site → select a specific area → select a specific location

9.4.4 Selection of a specific location from the Operations screen provides options to view details about that location.



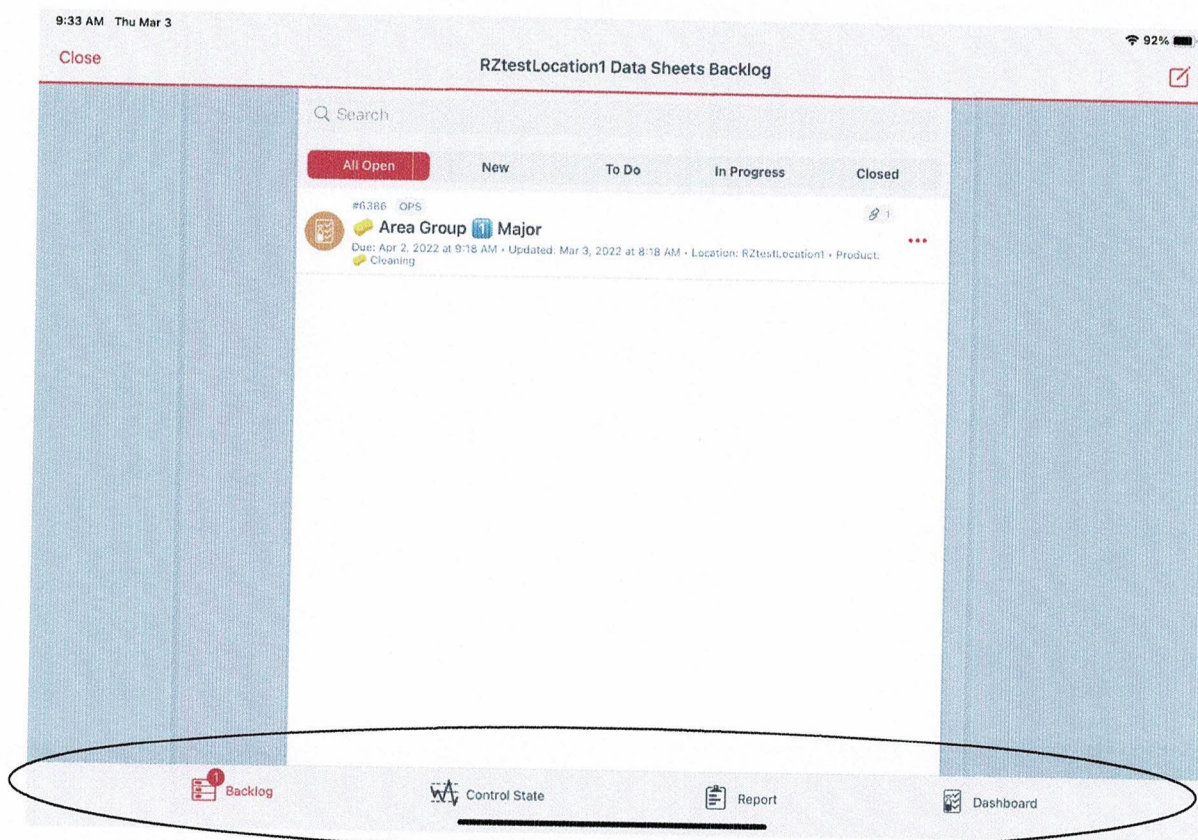
9.4.5 Swipe left or right to see other summary views for this location. Select options on the left of the screen to see other detail views. The image above displays a red box around the “Quality” option, indicating that there are data sheets ready for execution at this location.

9.5 Operations Quality Screen

9.5.1 Navigate to the Operations Quality Screen as follows:

9.5.1.1 Main Screen → Operations → select a specific location → Quality

9.5.2 The Operations Quality Screen is available by selecting the “Quality” option on the left side of the Operations Location Screen. The image below shows the default view after selecting this option.



9.5.3 At the bottom of this screen are options for viewing data sheets and information about data sheets.

Standard Operating Procedure Redzone General Use	SOP No C-111	Rev 1	Page 13 of 23
--	-------------------------------	------------------------	----------------------

9.6 Backlog Screen

9.6.1 Navigate to the Backlog screen as follows:

9.6.1.1 Main Screen → Operations → select a specific location → Quality → Backlog

9.6.2 The default view is “Backlog”. At the top of this Backlog view are options to search for and filter data sheets. This screen summarizes datasheets issued to the location.

Note: Some datasheets associated with what is active in this location may not appear here if they were not issued to the location and are intended for Quality to complete. To see all associated datasheets, use the Quality Dashboard.

9.7 Control State

9.7.1 Navigate to the Control State screen as follows:

9.7.1.1 Main Screen → Operations → select a specific location → Quality → Control State

9.7.2 The Control State option in the Operations Quality screen allows the view of SPC characteristics.

9.8 Quality Run Summary

9.8.1 Navigate to the Quality Run Summary as follows:

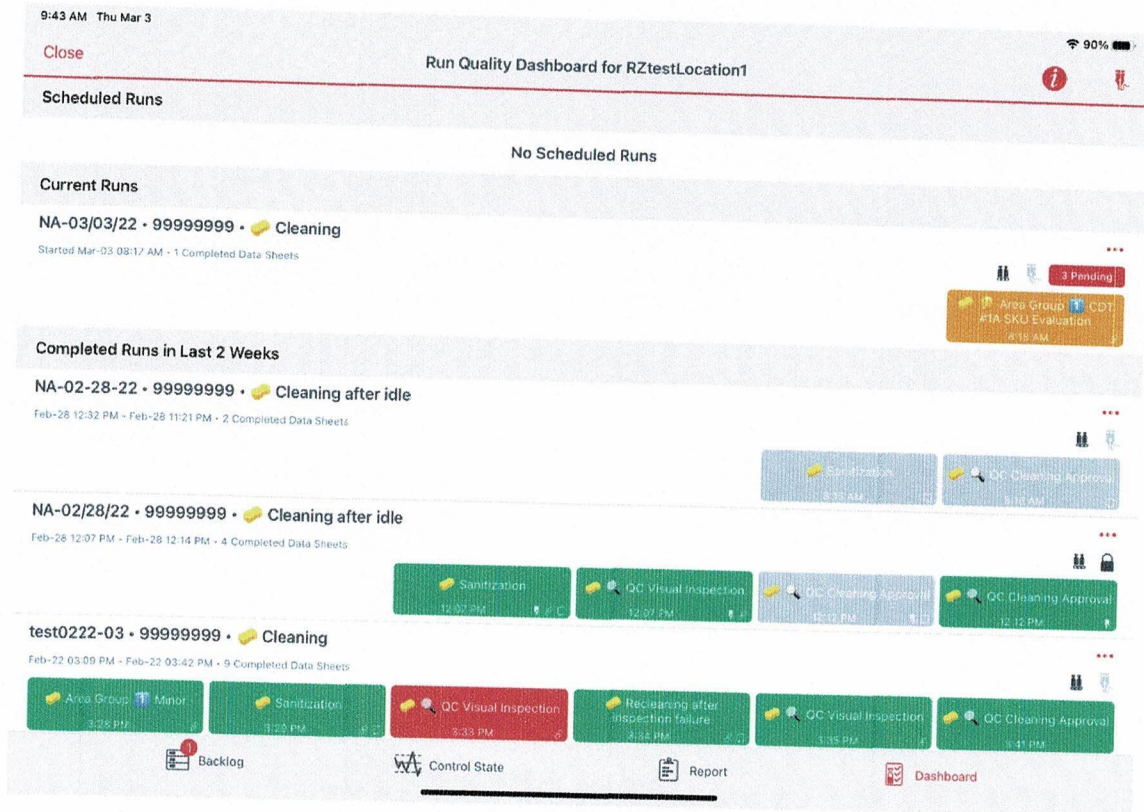
9.8.1.1 Main Screen → Operations → select a specific location → Quality → Report

9.8.2 See discussion of “Understanding the Quality Run Summary Screen/Report” in this procedure.

9.9 Operations Quality Dashboard

9.9.1 Navigate to the operations Quality Dashboard as follows:

9.9.1.1 Main Screen → Operations → select a specific location → Quality → Dashboard

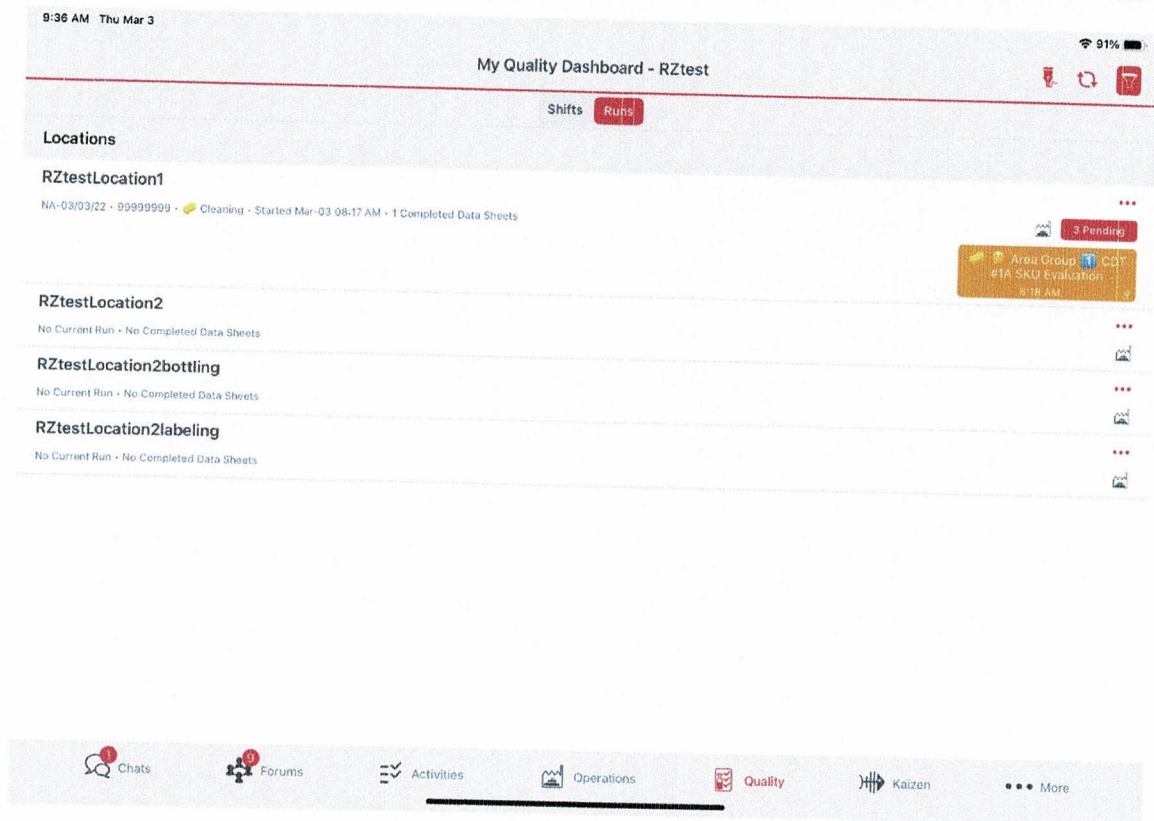


9.9.2 The Operations Quality Dashboard is similar to the Quality Dashboard accessed from the main menu, with the exception of the fact that it only displays information for the currently selected specific location. See the “Quality Dashboard” discussion in this procedure for more details.

10.0 Quality Dashboard

10.1 Navigate to the Quality Dashboard as follows:

10.1.1 Main Screen → Quality




10.2 The Quality Dashboard provides a summary of completed data sheets, indicating the status of the data sheet (Pass, Warn, Fail, Missed, Cancelled, or Voided). Each location displays the number of pending data sheets next to an ellipsis ●●● which, if selected, provides options for more detailed views as follows:

10.2.1 Pending Data Sheets (a shortcut to the pending data sheets for that specific location)

10.2.2 Run Quality Dashboard

10.2.3 Operations Page (a shortcut to the operations page for that location)

10.3 Each location line also displays a run sign off icon  that changes color based on sign off status (see color picture below with color description if printed in black and white).



Not Signed Off



Partial Sign Off



Production Sign Off



On Hold



Locked

10.3.1 Grey Sign Off icon: Not Signed Off

10.3.2 Yellow Sign Off icon: Partial Sign Off


10.3.3 Green Sign Off icon: Production Sign Off

10.3.4 Red Sign Off icon: On Hold

10.3.5 Black Padlock icon: Locked

10.4 Selection of the sign off icon displays screens to allow run sign off if the use has privileges to do so.

11.0 Data Sheets

11.1 Data sheets provide a mechanism to record data. RZ administrative personnel configure data sheets in the *RZ Admin* application. The behavior of a data sheet depends upon configuration, but for most applications, data sheets require an electronic signature upon completion. Configuration of data sheets often includes automatic initiation of a data sheet based upon some event. Data sheets are often configured to initiate to a specific area and are associated with a specific run. For example, a data sheet may start when a production run starts. Data sheets may start at specific times or intervals and may not be associated with a specific run. For example, a data sheet may be initiated to record weekly checks. Operators may start data sheets manually as needed by clicking the square pencil  where available.

11.2 Data sheets are visible and available in the following locations:

11.2.1 Main Screen → Activities

11.2.2 Main Screen → Operations → choose a specific location → Quality → Report

11.2.3 Main Screen → Quality → Ellipsis ●●● on a specific location → Pending Data Sheets

11.2.4 See also “General Review Options” in this procedure for other ways to navigate to a data sheet.

12.0 Data Sheet Types

12.1 There are three types of data sheets. The table below defines the behavior of each type.

Data Sheet Type	Scoring method	Included in Quality Dashboard	Included in Sign Off Dashboard	Must be linked to a production run
Quality Check	Pass / Fail	Yes	Yes	Yes
Production Check	Pass / Fail	No	No	No
Audit	Numeric Score	No	No	No

12.2 Quality Check data sheets are associated with a production run and therefore a production batch number. Quality Check data sheets include activities like a run startup check, a run process check, etc.

12.3 Production Checks are not associated with a run. These checks are independent of a specific production run or batch number and include activities like a scale daily check, equipment calibration, or an environmental monitoring check.

Standard Operating Procedure Redzone General Use	SOP No C-111	Rev 1	Page 18 of 23
---	-------------------------------	------------------------	----------------------

12.4 Audit data sheets are also independent of any specific production run or batch number. The key difference for Audit data sheets compared to the other two data sheet types is that Audit data sheets provide a score when completed.

13.0 Filters

13.1 RZ provides filters (see symbol in the title of this section) on many of the user interface screens. The filter options vary depending upon the application; however, there are common features across most applications of the filter icon.

13.2 After first selecting the filter icon:

13.2.1 A list of pre-defined and/or pre-saved filters is listed (as applicable)

13.2.2 A plus “+” sign in the top right provides the ability to add new filters

13.3 An ellipsis ●●● next to each pre-defined filter provides additional options like:


13.3.1 Set as default

13.3.2 Edit

13.3.3 Delete

13.3.4 Cancel (which backs out of the dialog brought up by selecting the ellipsis)

13.4 Selecting a pre-defined or pre-saved filter executes that filter.

13.5 Creating a new filter or editing an existing filter brings up a dialog with filter options. Edit these options as needed. Pressing the play icon () in the upper right corner allows for options like:

13.5.1 Save as Default and Run

13.5.2 Save and Run

13.5.3 Run Only (which allows running without saving selected filter options)

13.5.4 Cancel (which backs out of the dialog brought up by selecting the play icon)

14.0 General Review Options

14.1 Under the “More” tab at the bottom of the main screen, RZ provides tools for searching and reviewing data and data sheets collected in RZ. The sections below provide details about these tools.

14.2 Historical Report Search

14.2.1 The historical report search tool allows the use of Filters to find and review Shift Reports, Run Reports, and Quality Run Reports. This tool is available from the following screen selection steps:

14.2.1.1 Main Screen → More → Historical Report Search

14.3 Data Sheet History

14.3.1 The data sheet history tool allows the use of Filters to look at historical data across runs and based on specific data sheet templates. This tool is available from the following screen selection steps:

14.3.1.1 Main Screen → More → Data Sheet History

14.4 SPC Report Search

14.4.1 The SPC report search tool allows the review of SPC data across runs in a specific location for a specific product, and a specific characteristic. This tool is useful for tracking performance of these parameters. This tool is available from the following screen selection steps:

14.4.1.1 Main Screen → More → Data Sheet History

15.0 Understanding the Data Sheet “Action” screen

15.1 The data sheet action screen is available as described for “Data Sheets” in this procedure and is only available for unexecuted data sheets. Each data sheet has an action screen before execution. At the top of the screen is a unique action number assigned to that data sheet. The action number will remain with the data sheet after execution and is a unique identifier. At the top of the action screen is a “Continue” option. Selection of the continue option opens the data sheet for execution and allows the user to enter data. The action screen summarizes details about the data sheet, including:

15.1.1 Data sheet name

15.1.2 Data sheet due date (all data sheets have a due date and will close as “missed” if not executed before that due date. The time frame given to complete a data sheet is set up during data sheet configuration by an RZ admin)

15.1.3 Product Name and SKU (if applicable)

15.1.4 Run ID / Batch Number (if applicable)

15.1.5 Run Location (if applicable)

15.1.6 Comments, including references to linked datasheets (if applicable)

16.0 Understanding the “Data Sheet Results” screen and reports

16.1 The data sheet results screen is available as described for “Data Sheets” in this procedure and is only available for fully executed data sheets. Each data sheet generates a “Data Sheet Results” report after execution. The data sheet action number is available in small print at the top of the data sheet. At the top of the screen are options to “Retest” or “Void” the data sheet. This report summarizes details about the data sheet, including:

<p style="text-align: center;">Standard Operating Procedure Redzone General Use</p>	<p style="text-align: center;">SOP No C-111</p>	<p style="text-align: center;">Rev 1</p>	<p style="text-align: center;">Page 21 of 23</p>
--	---	--	---

- 16.1.1 Product Name and SKU (if applicable)
- 16.1.2 Run ID / Batch Number (if applicable)
- 16.1.3 Run Location (if applicable)
- 16.1.4 Dates, times, and user associated with initiating, executing, authenticating, and signing the data sheet
- 16.1.5 Data sheet results
- 16.1.6 Overall data sheet status (i.e. Pass, Warn, Fail, Cancel, Miss, and Void)
- 16.1.7 Comments and attachments along with the date, time, and user that added them
- 16.1.8 Links to other data sheets as applicable are included in the comments section. RZ adds Links when one data sheet initiates another data sheet (e.g. a retest, or a data sheet initiated by a trigger). These links are auto generated in the comments section of the data sheet.
- 16.2 This screen is interactive, providing more detail and other screens upon selection of a selection in the report screen.

17.0 Understanding the “Quality Run Summary” screen and reports

- 17.1 The quality run summary report is available from the following screen selection steps:
 - 17.1.1 Main Screen → Operations → Operations Location → Quality → Report
 - 17.1.2 Main Screen → Quality → Ellipsis ●●● on specific location → Quality Run Summary
 - 17.1.3 Main Screen → More → Historical Report Search → filter with “Quality Run Report” option selected → select specific run
- 17.2 The top of the report identifies:

- 17.2.1 The location that the run occurred in
- 17.2.2 The product name
- 17.2.3 The SKU for the product
- 17.2.4 The Run ID (i.e. batch number)
- 17.3 The beginning of the report summarizes (both graphically and in table format) the number of each data sheet template started for the run in the following groupings:
 - 17.3.1 Total
 - 17.3.2 Pass – Green in graphical display
 - 17.3.3 Warn – Orange in Graphical display
 - 17.3.4 Fail – Red in graphical display
 - 17.3.5 Cancel – Gray in graphical display
 - 17.3.6 Void – Gray in graphical display
 - 17.3.7 Miss – Black in graphical display
- 17.4 The rest of the report contains detail information for the run and data sheets initiated in the run. This screen is interactive providing more detail and other screens upon selection of a section in the report screen. For example, selection of s specific data sheet will open the “Data Sheet Results” screen for that data sheet.

18.0 Electronic Signature

- 18.1 Before getting an RZ profile, you must complete form QS-116-F1 Electronic Signature Acknowledgement and Consent by providing a handwritten signature on that form.

19.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	03/07/22	New procedure.	N/A	K. Burris
1	03/06/24	Corrected typographical errors (OOE) in section 8.2.7.1.	CC-24-0109	K. Burris