

	<b>Standard Operating Procedure</b> <b>Redzone Administration Activities</b>		<b>SOP Number</b> <b>C-108</b>	<b>Revision</b> <b>0</b>
			<b>Effective Date</b> 04/01/22	<b>Page</b> <b>Page 1 of 14</b>
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## 1.0 Purpose

The purpose of this procedure is to define Redzone administration activities.

## 2.0 Scope

This procedure applies to administration activities associated with Redzone.

## 3.0 Responsibility

3.1 It is the responsibility of all employees provided with permissions to use the ***RZ Admin*** application to adhere to the requirements of 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.
- 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 data sheets, 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 **Data sheet** – Unless explicitly stated otherwise, a data sheet is an RZ component of the RZ Compliance Module that is configured in *RZ Admin* and used in *Redzone* to collect data.
- 4.7 **Tableau** – Tableau is an interactive data visualization software company / tool focused on business intelligence. The tool is used to query relational databases, online analytical processing cubes, cloud databases, and spreadsheets to generate graph-type data visualizations.
- 4.8 **SPC** – Statistical Process Control; a method of measuring and controlling quality by monitoring the manufacturing process. Quality measurements recorded in data sheets are evaluated against control statistical control rules to identify trends before data is out of specified limits.
- 4.9 **Installation Qualification (IQ)** – IQ verifies that equipment or a system is installed according to the manufacture’s specifications or installation checklist.
- 4.10 **Operational Qualification (OQ)** – OQ verifies that equipment or system performance meets all identified user requirements as defined in a URS document. OQ is performed after meeting all IQ requirements.
- 4.11 **Performance Qualification (PQ)** – PQ verifies that user requirements as defined in a URS have been verified similar to OQ. The difference is that PQ evaluates the system as a whole while OQ focusses on units individually.
- 4.12 **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.
- 4.13 **Biometrics** – Biometrics mean a method of verifying an individual’s identity based on measurement of the individual’s physical feature(s) or repeatable action(s) where those

features and/or actions are both unique to that individual and measurable.

- 4.14 **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.
- 4.15 **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.
- 4.16 **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.
- 4.17 **cGMP** – Current Good Manufacturing Practices

## 5.0 References

- 5.1 C-105, SOP, Protocol and Report Documentation Requirements
- 5.2 C-403, SOP, Change Control Procedure
- 5.3 C-111, SOP, Redzone General Use

## 6.0 Procedure

- 6.1 Overview
- 6.1.1 Use the backend *RZ Admin* application to complete development activities associated with this procedure. Use the *Redzone* application to complete testing activities associated with this procedure.

6.2 RZ Knowledge Base

6.2.1 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.

6.3 Verification of Product Characteristics

6.3.1 RZ provides the ability to assign product characteristics to products. Product characteristics are available to data sheets and provide a mechanism to test data entered into a data sheet against control and specification limits. Evaluate the connection of a data sheet to the proper characteristics during the PQ / Verification process of the data sheet. Verify that product characteristic values entered are correct for that product during the review and approval process for the applicable product documentation (e.g. product profile, test ticket, etc.). Include product characteristic verification documentation with those supporting documents (i.e. the initial approval documentation, or change control documentation) as applicable.

6.4 Design and Create Data Sheets and Triggers

6.4.1 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

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

6.4.3 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.

6.4.4 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.

6.4.5 Create the appropriate type of data sheet to fit the needed function. Use control limits on fields when applicable. Use triggers to automate compliance with applicable procedures. Attachment 1 defines fields available for use within data sheets. Attachment 2 defines triggers available for use with data sheets. Review data sheets during the design phase to ensure compliance with applicable procedures. Procedures may need to include adoption of RZ data sheets into the process.

## 6.5 PQ Conditions

6.5.1 Installation Qualification (IQ) and Operational Qualification (OQ) of RZ validate the basic functionality of RZ and do not need repeating. Further Performance Qualification (PQ) documentation of the application of RZ to specific cGMP functions is dependent upon the complexity and purpose of the application. The following defines when a PQ report is required in a report as defined later in this SOP and when it is not.

**Note:** PQ activities (i.e. verification that the RZ works as intended) is always required. Documentation of that verification is defined here.

6.5.1.1 A PQ Report is required only for automating a cGMP process by RZ. Automation includes:

- When RZ performs cGMP calculations

- When RZ determines the outcome of a cGMP test (i.e. checking results to Pass, warn, or Fail)
- When RZ schedules GMP work or performs a cGMP function and Ion trusts that schedule or work without any other safeguard to make sure that work or function happens (i.e. the automatic trigger of a data sheet based on specific events)

6.5.1.2 Ion Labs may choose to write a PQ report, but a PQ report is not required for the following applications of RZ:

- RZ data sheets used for non-GMP purposes
- RZ data sheets that only collect data (i.e. no automation)
- RZ data sheets that include automation, but that automation is not a cGMP requirements. For example, RZ triggers may provide alerts or messages that are for convenience, but are not a cGMP function.
- Minor modification of a previously verified RZ application (see further discussion on this topic later in this procedure).

## 6.6 RZ Process – PQ Steps

6.6.1 When creating or modifying RZ Compliance Components (i.e. data sheets, triggers, and/or reactions), always test and verify that they function as intended before deployment for cGMP activity use (i.e. complete PQ steps defined here).

**Note:** This activity may require documentation in a PQ report as defined later in this procedure. Consider and address the following during PQ activities as applicable.

- 6.6.1.1 When possible, test new components using “RZ Test” components (i.e. areas, locations, products) rather than real components.
- 6.6.1.2 When using real components to test new components, add comments as applicable, indicating that the activity is for test purposes and not associated with real production activities.
- 6.6.1.3 For complicated trigger/reaction scenarios, be sure to test all applicable paths. For example, test passing, warning, and failing results if the triggers involved should behave differently under those conditions.
- 6.6.1.4 Test data sheets that connect to product characteristics to ensure that they connect as expected.
- 6.6.1.5 Test data sheets that contain calculations to ensure that formulas work as expected.
- 6.6.1.6 Consider the steps necessary to deploy the process in RZ.
- 6.6.1.7 Ensure that the RZ components align with the requirements of applicable procedures and regulations associated with the intended purpose.
- 6.6.1.8 Update procedure as necessary to provide operators with necessary instructions to use the RZ components.

## 6.7 Redzone PQ Report Requirements

- 6.7.1 Upon completion of PQ activities for a cGMP RZ process as defined in this procedure, complete a PQ report. The PQ report must include, at a minimum, the following features:
  - 6.7.1.1 Assign a report number and comply with report requirements as defined in SOP C-105 Protocol and Report Documentation Requirements.

- 6.7.1.2 Reference this procedure as the source of PQ requirements for the report.
- 6.7.1.3 List all RZ components subject to the PQ. Cover any number of components in the same report as needed. It is best practice to group components into the same report by function, process, or purpose.
- 6.7.1.4 List procedures that the RZ components support. Verify that the functionality of the components align with procedure requirements. Procedures may need revision to accommodate RZ as part of the process.
- 6.7.1.5 Describe the RZ components and intended use. Flow charts are not necessary for simple PQs, but are best practice for complicated processes.
- 6.7.1.6 Describe the PQ steps used. It is not necessary to list every step in detail. Do include:
- Who was involved in the PQ steps described and the dates the activities occurred.
  - Provide enough detail to allow finding evidence of the steps taken within RZ as applicable.
- 6.7.1.7 It is not necessary to record screenshots to document PQ activities.
- 6.7.1.8 Describe the deployment plan as applicable.
- 6.7.1.9 Define at least two signatures on the report that indicate Done By and Verified By with regard to the PQ activities. At least one signature on the report must be a quality signature.

6.8 Modification to Previously Verified RZ Processes

6.8.1 Major modifications to a previously verified application of RZ to a cGMP system require re-execution of the PQ process as described here. Minor modifications do not require re-execution. The discussion of PQ Conditions are a good definition of the intent of PQ as it applies to RZ. If the changes made fall into examples of a system that would require PQ, then re-execution is required. If not, the re-execution is also not required. The list that follows are examples of changes that would not necessarily require documented re-qualification:

6.8.1.1 Changes to test on a data sheet

6.8.1.2 Adjustments to triggers or data sheets to include new products or locations

## 6.9 RZ Test Components

6.9.1 RZtest...” components exist in the live RZ system only for training and testing purposes. Some of these components require a username and password to create the component (i.e. Area, Location, or User Components). IT is responsible for managing all users and the RZtestUser account is disabled during normal operations. The username and password for Areas and Locations is available to allow a system login as an Area or Location. TRZ does not allow this login any administration privileges. Ion Labs does not use this feature. Do not distribute passwords for Locations or Areas. Do not distribute passwords for Locations or Areas.

## 6.10 Understanding Revision History in the RZ Admin Application

6.10.1 The revision history of components (i.e. people, places, products, shifts, data sheets, and triggers) in the RZ Admin application have a similar method of displaying revision history. The application stores revisions to these components under a revision section on the same screen where editing of these components occurs. The system groups changes based on the date and time the user saves the changes. A single header includes the revision number, the user that made the change and the date and time for the “save” event. Under that header are all the changes listed individually with a colored dot next to the change. The color of the dot has the following meanings:

6.10.1.1 Green dot = fields / values added

6.10.1.2 Red dot = fields / values removed

6.10.1.3 Orange dot = fields / values changed

6.10.2 Use revision history documented in RZ in conjunction with other system documentation (e.g. the initial approval documentation, or change control documentation) to investigate and confirm deviations, errors, and routine changes.

## 7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	03/14/22	New procedure.	N/A	K. Burris

## 8.0 Attachments

8.1 Attachment 1 – Redzone Data Fields

8.2 Attachment 2 – Redzone Triggers and Reactions

**Attachment 1 – Redzone Data Fields**

Table 1: Field Types

<b>Field Type</b>	<b>Description</b>
Keyboard	The user may enter text from the device keyboard.
Formatted Text	The user may enter text from the device keyboard; however, the format of the text entered must comply with a “mask” custom defined for the field. For example a mask of “(###) ###-####” would force a typical phone number format. A mask of “ION-####” would only allow a four-digit asset number with “ION-“preceding the asset number.
Whole Number	The user may enter a whole number.
Decimal Number	The user may enter a decimal number. This field allows the control of the number of digits store through the “Decimal Precision” option for the data field defined during datasheet design.
Date (Day & Time)	The user may enter a date and time
Date (Day & Year)	The user may enter a date without a time.
Photo	Allows the insertion of a photo taken from the device (iPad) in real time
Photo or Camera Reel	Allows the insertion of a photo taken from the device (iPad) in real time or a photo chosen from a previously taken photo
Barcode	Allows taking a scan of a barcode or QR code and will input the result into the field.
Match List	Allow selection from a list of options defined for a product characteristic.
Option List	Allow selection from a previously defined option list. Option lists are defined in the Redzone administration app.
Numeric Sample Set	The user may enter a series of numbers. The field allows control of the count of numbers the user enters through a “Sample Size” setting for the field. An “aggregation” setting for the field also defines an aggregation method as one of the following (Mean, Median, Mode, Max, Min, Sum, or Range).
Expression	The user may define an expression. The expression may consist of other fields on the datasheet and the functions defined in <b>Error! Reference source not found.</b>
Secondary Test	This field is used in conjunction with a Numeric Sample Set field. The secondary test applied a different aggregation setting to the same data collected in the Numeric Sample Set field.

### Attachment 1 – Redzone Data Fields

**Error! Reference source not found.** below defines functions available for use in a RZ Expression field type

Table 2: Expression Functions

Function	Description
Add (+)	Addition
Subtract (-)	Subtraction
Multiply (x)	Multiplication
Divide (÷)	Division
Parenthesis	Opening parentheses “(”, and closing parentheses “)” may be used to control the order of operation within the expression.
Maximum	The maximum of values contained within the function
Minimum	The minimum of values contained within the function
Mean	The mean of values contained within the function
Mode	The mode of values contained within the function
Range	The range of values contained within the function
Sum	The sum of values contained within the function
Product	The product of values contained within the function
Count	The count of values contained within the function
Reference	Reference other data fields on the same data sheet.

### Attachment 1 – Redzone Data Fields

**Error! Reference source not found.** below lists options available for use with RZ fields. These options may be:

- Omitted
- Applied specifically to the field in the datasheet, or
- Applied as a product characteristic specific to the product associated with the instance of the datasheet

Table 3: Data Field Options

Option	Description
Decimal precision	This option defines the number of places after the decimal point that the system will use to evaluate this field against limits defined by the next rows of this table.
Lower Reasonable limit	The lowest value considered as a reasonable entry. Values lower than this will prompt the user that this may not be a reasonable. This limit may prevent entry errors.
Lower spec limit	The lowest value allowed that still meets the specification. Values lower than this will produce a FAIL status.
Lower control limit	The lowest value allowed that is in control. Values lower than this will produce a WARN status. The values may be set or based on SPC calculation.
Spec Standard	This represents the specification value. This may be different from the target value. For example, a specification may be 100% while a target may be 105% for a product formulated with a 5% overage.
Target value	This represents the expected target value. See also the description of Spec Standard.
Upper control limit	The highest value allowed that is in control. Values higher than this will produce a WARN status. The values may be set or based on SPC calculation.
Upper spec limit	The highest value allowed that still meets the specification. Values higher than this will produce a FAIL status.
Upper reasonable limit	The highest value considered as a reasonable entry. Values higher than this will prompt the user that this may not be a reasonable. This limit may prevent entry errors.

**Attachment 2 – Redzone Triggers and Reactions**

Table 4: Triggers

<b>Trigger Type</b>	<b>Description</b>
Shift Started	The trigger will fire upon the start of a shift.
Shift Ending	The trigger will fire once the shift is ended.
Shift uptime	Define an interval where the trigger will fire based on uptime during the shift.
Shift downtime	Define an interval where the trigger will fire based on total downtime during the shift.
Shift continuous downtime	Define an interval where the trigger will fire based on a period of continuous downtime during the shift.
Shift elapsed time	Define an interval where the trigger will fire based on elapsed time during the shift (regardless of uptime or downtime).
Shift units produced	Define an interval where the trigger will fire based on the total number of units produced during the shift.
Run started	The trigger will fire upon the start of a run
Run ending	The trigger will fire once the run is ended.
Run uptime	Define an interval where the trigger will fire based on uptime during the run.
Run downtime	Define an interval where the trigger will fire based on total downtime during the run.
Run continuous downtime	Define an interval where the trigger will fire based on a period of continuous downtime during the run.
Run elapsed time	Define an interval where the trigger will fire based on elapsed time during the run (regardless of uptime or downtime).
Run units produced	Define an interval where the trigger will fire based on the total number of units produced during the run.
Run percentage complete	Define a specific percentage of completion where the trigger will fire based on the scheduled quantity of the run.
Run sign off incomplete	Define an interval where the trigger will fire if the run is not signed off or locked
Datasheet completed	Specify a datasheet and result that will trigger this data sheet to be created.
Data item completed	Trigger will fire based on the defined result of a specific data item on a datasheet.
Calendar	Can configure trigger to fire on a specific month, day of the month or week, and time of day.
Recurring	Specify a start date/time, and define an interval for the trigger to fire regularly.
Problem created	Trigger will fire upon creation of a problem – based on Problem Type, Group, Category, or Asset.
Cycle update	Trigger will fire based on the defined result of a cycle – can be based on specific assets or products.