	Standard Operating Procedure		SOP Number C-107	Revision 0
	Redzone Reviewer Activities		Effective Date 04/01/22	Page Page 1 of 8
Written by/ Date <i>K. Summers 03/14/22</i>		Reviewed by/ Date <i>Pam Run 03/14/22</i>		Approved by/ Date <i>Denis [Signature] 03-15-22</i>
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1.0 Purpose

The purpose of this procedure is to define the review and signoff requirements for Redzone data sheets and runs.

2.0 Scope

This procedure only applies to data sheets and runs associated with cGMP activities. This procedure does not cover the review of paper documents or documents generated by systems other than Redzone.

3.0 Responsibility

- 3.1 It is the responsibility of all employees engaged in RZ review and signoff activities (i.e. people with “Quality Sign Off Permission” set to “Data Sheet” or “Run”) to comply with this procedure.
- 3.2 It is the responsibility of Quality Management to maintain this procedure to ensure that it reflects current practices.

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 **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 statistical control rules to identify trends before data is out of specified limits.
- 4.8 **Handwritten Signature** – Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the 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.
- 4.9 **Digital Signature** – Digital signature means an electronic signature based upon cryptographic methods 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.
- 4.10 **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.
- 4.11 **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.

4.12 **cGMP** – Current Good Manufacturing Practices

4.13 **Sign Off** – Approval of quality checks conducted during a completed run.

4.14 **SOP** – Standard Operating Procedure

5.0 References

5.1 A-106, SOP, Documentation Guidelines for cGMP Records

5.2 C-111, SOP, Redzone General Use

6.0 Procedure

6.1 Overview

6.1.1 Ion Labs uses RZ data sheets to replace logbooks and forms used by conventional paper-based systems. RZ is capable of automating the initiation of data sheets and able to send out alerts based on various events or data sheet status. This automation helps ensure compliance with procedures and regulatory requirements.

6.1.2 This procedure covers the review and sign off process for RZ data sheets and runs. RZ data sheets are initiated automatically or manually depending upon the process. RZ data sheets may be associated with a production run (e.g. run startup check, run process check, etc.) or may be independent of a specific production run (e.g. scale daily check, environmental monitoring check, audit check, etc.). most data sheets require authentication (i.e. digital signature) from the user finalizing the data sheet. This is equivalent to a “done by” handwritten signature. The design of some data sheets include the check of activities performed previously. Authentication of these activities is equivalent to a “verified by” handwritten signature. The design of some data sheets may

require reviews and send out review notifications. This is equivalent to a “reviewed by” handwritten signature. The RZ run sign off process also documents reviews and review signatures.

6.1.3 Ion Labs uses RZ to track each production run. Operators start a RZ shift and, a RZ run where they enter the production Batch Number as the RZ Run ID. Data sheets initiated as applicable throughout the run are available for review and signoff as defined in this procedure.

6.1.4 Standard Operating Procedures (SOPs) control the use of RZ data sheets. Process specific SOPs may provide details about the use of RZ data sheets and review requirements. Process specific SOPs override any general RZ SOP requirements that conflict with those more specific SOPs. Use the frontend *Redzone* application to complete 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 Review for Good Documentation Practices (GDP)


6.3.1 RZ data sheets used in cGMP runs are electronic records used to capture cGMP activities. RZ provides the ability to correct, (i.e. “retest”) a data sheet to correct entries. RZ also provides mechanisms to cancel a data sheet, and void a data sheet. These activities require appropriate comments and/or corrective actions unless the reason is obvious. If a RZ data sheet design includes a trigger to initiate another data sheet to address one of these issues, that additional data sheet may provide the necessary information and avoid the need for a comment.

6.4 Review Exceptions


6.4.1 RZ graphical displays of data sheet status (i.e. Pass, Warn, Fail, Cancel, Miss, and Void) makes it easy to identify data sheets with an exception that would require a more critical review. Consider all data sheets with a status other than “Pass” a data sheet that warrants a critical review unless the design of the data sheet expects these status conditions as part of the process.

6.5 Review Corrective Actions

6.5.1 Review of exceptions may identify the need for corrective actions. Review corrective actions and ensure that actions taken are appropriate.

6.6 Run sign off process 

6.6.1 The remainder of this procedure provides sections that describe specific aspects of the run signoff process. Each run requires sign off before release of product associated with that run or before release of the associated activity (e.g. a cleaning run). Before signing off on a run, ensure that associated data sheets are reviewed and compliant. If necessary, have corrections or comments added before completing final signoff.

6.7 Run sign off options and status 

6.7.1 RZ provides three levels of Sign Off described here:

6.7.1.1 Sign Off - This option can apply to portions of the run or the entire run. It indicates that review is complete and acceptable for data sheets with this status. It is possible to change this status to either “On Hold” or “Lock”

6.7.1.2 On Hold - This option can only apply to the entire run. It indicates that the run is not suitable for release until additional action is completed. It is possible to change the status to Lock, but it is not possible to change the status back to Sign Off

6.7.1.3 Lock - This option can only apply to the entire run. The system does not allow further sign off status changes once a run is “locked”

6.7.2 Redzone changes the color of the Run Sign Off icon (see symbol in the title of this section) displayed next to any given run based on the sign off status (see color picture below with color description if printed in black and white).

6.7.2.1 Grey Sign Off Icon: Not Signed Off

6.7.2.2 Yellow Sign Off Icon: Partial Sign Off

6.7.2.3 Green Sign Off Icon: Production Sign Off

6.7.2.4 Red Sign Off Icon: On Hold

6.7.2.5 Black Padlock Icon: Locked




Note: Comments are available for addition to the run or individual data sheets regardless of run signoff status.

6.8 Access to the “Sign Off Dashboard” and “Run Sign Off” Screens

6.8.1 The “Sign Off Dashboard” provides a list of all runs yet to be “locked.” The “Run Sign Off” screen provides sign off options for specific runs. The following steps provide access to these screens:

6.8.1.1 Access the “Quality Dashboard” from the “Quality” tab at the bottom of the main screen.

- 6.8.1.2 Select the Run Sign Off icon () form the Quality dashboard. Select a specific run or multiple runs to access the “Run Sign Off” screen.
- 6.8.1.3 Select the “More” tab at the bottom of the main screen and then select “Sign Off Dashboard.” Select a specific run or multiple runs to access the “Run Sign Off” screen.
- 6.8.1.4 Select the “More” tab at the bottom of the main screen and then select “Historical Report Search.” Apply an appropriate filter and navigate to the run of interest. If the run is not already “locked,” the Quality Run Summary screen provides a “Sign Off” option at the top of the screen. This method does not provide access to the Sign Off Dashboard, but does navigate to the “Run Sign Off” screen for a specific run.

6.9 Run Sign Off Steps

- 6.9.1 After selecting a run or multiple runs to sign off, proceed to review the data sheets associated with the run. See other sections of this procedure for details and requirements for reviewing data sheets. Select one or more data sheets to sign off and select the appropriate sign off option (i.e. Sign Off, Hold, or Lock) and then choose “Sign Off” to complete the process. The system will ask for “Sign Off Authentication” for you to provide your username and Pin or Password. After authentication, the selected data sheets and runs contain the updated sign off status and identifies the user completing the signoff function.

6.10 Export

- 6.10.1 RZ provides export capabilities (see export icon in the title of this section) on many of the user interface screens. After selecting the export icon a dialog screen appears with export options. These options may vary depending upon applications installed on the device, but should include Copy, Markup, Print, and Save to Files among other options. Choose the appropriate tool and follow

additional prompts as applicable. Other Ion Labs SOPs may require export or printing of RZ reports or data sheets in specific formats or using specific tools.

Note: It is possible to configure one or more email address to receive a “Quality Run Summary” report after a Run Sign Off “Lock” activity is complete. This is the same as exporting the report to an email.

7.0 Revision History

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