

	Standard Operating Procedure		SOP Number C-106	Revision 0
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Written by/ Date <i>[Signature]</i> 01-07-22		Reviewed by/ Date <i>[Signature]</i> 01/05/22		Approved by/ Date <i>[Signature]</i> 01-05-22
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1.0 Purpose

This procedure defines the Redzone Information Technology security and compliance policy for Ion Labs, Inc.

2.0 Scope

This procedure only applies to users of the Redzone Compliance module in use at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of all employees to execute this policy in full and to report any violations of this policy to their manager or the Director of IT.
- 3.2 It is the responsibility of the Director of IT to report any violation of this policy to the appropriate manager, department, or committee. The Director of IT is also responsible for the maintenance of this policy.

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 datasheets, and define triggers.

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- 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 a RZ component of the RZ Compliance Module that is configured in ***RZ Admin*** and used in ***Redzone*** to collect data.
- 4.7 **IT** – Information Technology; the study or use of systems (especially computers and telecommunications) for storing, retrieving, and sending information.

5.0 References

- 5.1 QS-115, SOP, cGMP Electronic System Controls and Requirements
- 5.2 QS-115-F3, Form, Electronic Signature Acknowledgement and Consent
- 5.3 New User Setup Policy
- 5.4 Release to Production Policy

6.0 Procedure

- 6.1 Employee Onboarding
 - 6.1.1 The New User Setup policy governs all onboarding.
 - 6.1.2 Onboarding includes but is not limited to:
 - 6.1.2.1 Creation of user account
 - 6.1.2.2 Defining user permissions based on group
 - 6.1.2.3 Assigning equipment
 - 6.1.2.4 User training
 - 6.1.3 All parameters are documented in the New User Setup policy.
 - 6.1.4 All users have executed form QS-115-F3 Electronic Signature Acknowledgement and Consent prior to being assigned a user account.
- 6.2 Employee Offboarding
 - 6.2.1 User accounts are disabled immediately upon determination of duties or employment.

6.3 Device Release to Production

6.3.1 All equipment for processing Redzone applications meets or exceeds the Release to Production policy.

6.4 Apple ID

6.4.1 All users with personally assigned iPads or Apple devices will be issued a private iCloud account.

6.4.2 Users with shared devices will have a shared iCloud account.

6.4.3 All Apple devices will have and maintain strong passcodes for the unlock screen.

6.5 Passwords

6.5.1 For the RZ user account, the following requirements apply to passwords:

6.5.1.1 All passwords expire every ninety (90) days.

6.5.1.2 All passwords must contain at least one (1) capital letter.

6.5.1.3 All passwords must contain at least one (1) lowercase letter.

6.5.1.4 All passwords must be at least six (6) characters long.

6.5.1.5 All password resets are performed by the IT department upon request and verification.

6.5.2 Forgotten and Compromised Passwords

6.5.2.1 SOP QS-115 cGMP Electronic System Controls and Requirements requires that all employees using electronic passwords for cGMP systems protect and keep confidential user names and passwords used to access those systems.

6.5.2.2 All compromised or forgotten passwords must be reported to the IT department, who will then reset the password as required.

6.5.2.3 IT will inform management in the case of suspicion that someone other than the person assigned a username and password has used it to access systems or sign transactions.

6.6 RZ Permissions

6.6.1 The following are available permission settings:

6.6.1.1 Users and Permissions

6.6.1.1.1 This permission provides full admin access to all other permissions.

6.6.1.1.2 With this level of access, a user can view and edit basic configuration data on the Places, Products, and Shifts tabs. Places includes access to Sites, Areas, Locations, Problems and Assets, and Manufacturing Types. Products access includes the ability to edit product data such as SKUs, costs, product characteristics, and unit of measure conversions.

6.6.1.1.3 This access level also includes the ability to define shifts, and view and edit the Apple TV configurations and Highlights.

6.6.1.2 Places, Products, & Shifts

6.6.1.2.1 With this level of access, a user can view and edit Production Checks and Audits. Along with the ability to manage characteristics, option lists, and Quality Preferences.

6.6.1.2.2 If utilizing Base Settings, a user with this access level will have the ability to view and edit the Base Settings sheets and defined settings.

6.6.1.3 Production Checks & Base Settings

6.6.1.3.1 With this level of access, a user can view and edit Production Checks and Audits. Along with the ability to manage characteristics, option lists, and Quality Preferences.

6.6.1.3.2 “Base Settings” is no longer a feature in the Compliance module. It has been moved to the Reliability module.

6.6.1.4 Quality Checks

6.6.1.4.1 With this level of access, a user can view and edit Quality Checks only. Along with the ability to manage characteristics, option lists, and Quality Preferences.

6.6.1.5 Maintenance Tasks

6.6.1.5.1 With this level of access, a user can view and edit Maintenance Tasks only. Along with the ability to manage characteristics, option lists, and Quality Preferences.

6.6.1.6 Triggers

6.6.1.6.1 With this level of access, a user can view and edit within the Triggers tab. Most likely this would be used in conjunction with another toggle enabled for one of the datasheet types.

6.6.1.6.2 Use these toggles individually, or combine them in custom combinations to create the desired levels of unique access for your users.

6.6.1.7 Send Links in Comments

6.6.1.7.1 This permission on its own does not provide any screens to be available in Admin, other than the Knowledge Base. It does allow the user to post clickable URLs in the Redzone app.

6.6.1.8 Quality Signoff Permission

6.6.1.8.1 This permission defines the level of quality sign-off available to the user.

- None = no quality sign off
- Datasheet = partial sign-off
- Run = full run or partial sign off

6.6.1.9 @Mention Notifications by Email

6.6.1.9.1 This permission allows the RZ @Mention app notifications to forward to the users email. An email must also be provided.

6.6.1.10 @Mention Notifications by SMS

6.6.1.10.1 This permission allows the RZ @Mention app notifications to forward to the user by text message. A phone number must also be provided.

6.7 Roles

6.7.1 Redzone does not have “Roles” that are applied to users. IT applies the following permission settings when individuals are assigned the roles in the table below:

<i>Permission</i>	<i>Operator / Lead</i>	<i>Production Admin / Management</i>	<i>Quality Inspector</i>	<i>Quality Reviewer</i>	<i>Quality Admin / Management</i>	<i>IT Admin</i>
Users & Permissions	No	No	No	No	No	Yes
Places, Products, & Shifts	No	Yes	No	No	Yes	Yes
Production Checks & Base Settings	No	No	No	No	Yes	Yes
Quality Checks	No	No	No	No	Yes	Yes
Maintenance Tasks	No	No	No	No	No	Yes
Triggers	No	No	No	No	Yes	Yes
Send Links in Comments	No	No	No	No	No	Yes
Quality Sign Off Permission	None	None	Run	Run	Run	Yes
@Mention Notifications by Email	As desired	As desired	As desired	As desired	As desired	Yes
@Mention Notifications by SMS	As desired	As desired	As desired	As desired	As desired	Yes

6.8 Backup

6.8.1 Redzone is a cloud-based system. Redzone is responsible for all data backup.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	01/04/22	New procedure.	N/A	D. Wagner