

## WarmMark QR Cloud 21 CFR Part 11 Validation

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## WarmMark QR Cloud 21 CFR Part 11 Validation

### Part A - GENERAL

#### Section 1: Objective

This document describes the scope of validation for verification of the SpotSee Cloud software system.

#### Section 2: Scope

The scope of this functional test script is the SpotSee Cloud software and database working in combination with inputs from a connected SpotSee sensor.

#### Section 3: Terms and Definitions

SpotSee Cloud software is referred to in this document as “the cloud” or “the software”.

#### Section 4: Equipment

Appropriate computer to access SpotSee Cloud.

A QR enabled sensor Bag or Box I.D. for account/user registration and confirmation of adding sensors to account.

#### Section 5: System Requirements

You will need the following hardware and software:

- A PC or fully compatible computer with JavaScript enabled.

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### Part B - FUNCTIONAL TESTS

#### Section 1: SpotSee Cloud User Registration

**Purpose:** To confirm user creates unique account.

**Item(s) Needed:** Label from bag or box of QR enabled sensor.

**Instruction:**

- Scan with mobile device the **Scan to Register QR code**,  
or **follow the link below the QR code**, on the bag or box label.

One person per organization should create an account off of the bag label. That person can then add users to the account with various permissions. The sensors are unique to the cloud which they are added to so it is important to have all persons who need access within the same cloud. An email will be sent to the user with a temporary password.

Follow the WarmMark QR Cloud User Manual to go through the New User Set Up process.

- Once logged in, position your cursor over the left side of the **Dashboard**, the **Navigational Bar** will appear.

- Select: **Admin > Users >**

Add User in top right corner.

*Attempt to create an account with the same username.*

*An error will appear.*

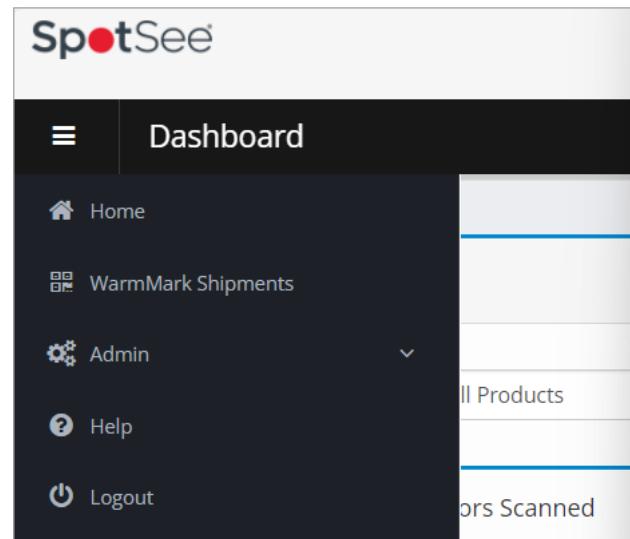
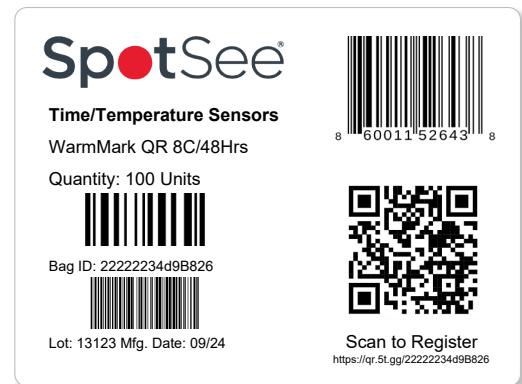


The screenshot shows a 'Add User' form. In the 'Username' field, the text 'testuser' is entered. Below the form, a red error message box displays the text 'User with this username already exists.'

**Acceptance Criteria Met:** Yes \_\_\_\_\_ No \_\_\_\_\_

*Attempt to create an account without complying to password controls. An error will appear.*

**Acceptance Criteria Met:** Yes \_\_\_\_\_ No \_\_\_\_\_



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### NOTE:

- Password reset is required every 6 months.
- If password is forgotten, select **Reset Password?** at login page and follow prompts.
- If username is forgotten, then contact SpotSee support at **techsupport@spotsee.io**.
- Five failed login attempts of a valid user's password will prompt an email from SpotSee notifying the user of the failed login attempts and prompting a password change.

### Section 2: User Controls, Electronic Signatures and Audit Trails

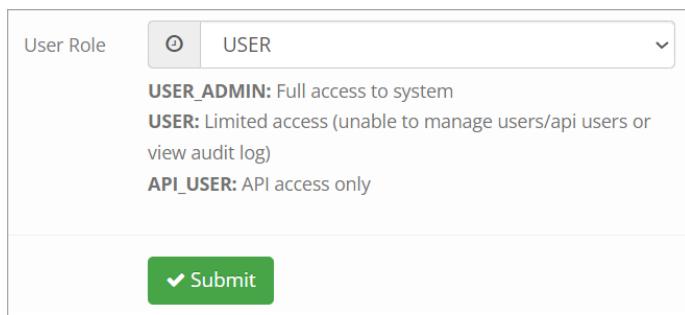
**Purpose:** Confirm user access restriction and tracking of record creation, modification and deletion.

**Item(s) Needed:** Access to SpotSee Cloud

#### User Controls -

##### Instruction:

- Position your cursor over the left side of the **Dashboard**, the **Navigational Bar** will appear.
- Select **Admin > Users > Add User** in top right corner.
- Complete fillable fields and select User in User Role drop down.



User Role

**USER\_ADMIN:** Full access to system  
**USER:** Limited access (unable to manage users/api users or view audit log)  
**API\_USER:** API access only

- Login as the newly created account that does not have User\_Admin access.
- Confirm by selecting Admin on the navigation bar that the Users option is not available.

*Repeat for other options as necessary.*

**Acceptance Criteria Met:** Yes \_\_\_\_\_ No \_\_\_\_\_

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### Electronic Signatures & Audit Trails -

#### A. User Creation

- Login to the original user which created the second user account without specific user accesses.
- Select **Admin > Audit Log** on the navigation bar.
- Confirm the user creation was captured in the audit log.

**Acceptance Criteria Met:** Yes \_\_\_\_\_ No \_\_\_\_\_

- Repeat for Modification

**Acceptance Criteria Met:** Yes \_\_\_\_\_ No \_\_\_\_\_

- Repeat for Deletion

**Acceptance Criteria Met:** Yes \_\_\_\_\_ No \_\_\_\_\_

Audit Log						
User	View All	Date	2024-10-28	to	2024-11-04	⟳
10	records per page	Search				
Name	Section	Action	Data		Audit Date	▼
Mason McWilliams	Reporting	Create	ReportType: Sensors, BagID: 0, Status: -1, ProductCode: , DateRange: 2024-10-04 00:00:00-2024-11-04 ...		2024-11-04 14:26:58	
Mason McWilliams	QRShipment	Create	SensorID: 22223WTVJ9A846, ShipmentID: Order#378HXW9		2024-11-04 14:13:40	
Mason McWilliams	Reporting	Create	ReportType: Shipments, DateRange: 2024-01-01 00:00:00-2024-10-31 23:59:59		2024-10-31 13:48:45	
Mason McWilliams	Reporting	Create	ReportType: SensorHistory, SensorID: 22223WTVK9C24R		2024-10-30 14:11:22	
Mason McWilliams	QRBag	Create	Allocate Bag, ID: 22222BpR4H8GT		2024-10-30 14:08:26	
Mason McWilliams	Users	Modify	Username: TWilliams -> TWilliams, Full Name: Tim -> Tim Williams, Email: twilliams@spotsee.io -> twi...		2024-10-28 20:46:43	
Mason McWilliams	Users	Create	Username: TWilliams, Full Name: Tim, Email: twilliams@spotsee.io, Temperature Scale: C, Date Format...		2024-10-28 20:46:34	

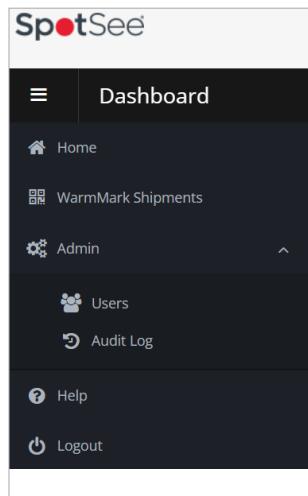
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### B. Adding Sensors to Cloud

If the original bag or box of QR enabled sensors was added via mobile scan of the QR code, which happens automatically after account creation/login, then the sensors may already be in the cloud.

If not, they need to be added manually.

- Position your cursor over the left side of the the **Dashboard**, the **Navigational Bar** will appear.
- Select > **WarmMark Shipments**.



- Then select **Add Sensors** in the top right corner of the page.

WarmMark Shipments										Add Sensors	
Product	All Products	Status	All Shipment Conditions	Dates	2024-10-04	to	2024-11-04	Search	Print	Print	Print
10	records per page	Search									
Product	Sensor I.D.	Shipment I.D.	Shipment Condition	Sensor Image	Location	Last Scan	Time Zone	History			
WarmMark	22223WTV8MB3D4		✓	<a href="#">View Image</a>	<a href="#">View Map</a>	2024-11-04 13:35:03		<a href="#">View</a>			
WarmMark	22223WTV78CH67		✗	<a href="#">View Image</a>	<a href="#">View Map</a>	2024-11-01 12:34:36	Europe/London	<a href="#">View</a>			

- Type or scan the bag or box I.D. located on the bag or box into the Add Bag I.D. field, select **Save**.

A screenshot of the 'Add Bag I.D.' dialog box. The dialog has a light gray background. At the top left is the text 'Add Bag I.D.'. Below it is a barcode scanner icon. To the right is a text input field with a small pencil icon. At the bottom are two buttons: a green 'Save' button and a red 'Close' button.

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- Once successfully adding, select **Admin > Audit Log** from the navigation bar.
- Confirm the record creation was captured.

**Acceptance Criteria Met:** Yes\_\_\_\_\_ No\_\_\_\_\_

Name	Section	Action	Data	Audit Date
Mason McWilliams	QRBag	Create	Allocate Bag. ID: 222222Bx09/38X	2024-10-28 18:37:34

### C. Shipment I.D. Records

- Position your cursor over the left side of the **Dashboard**, the **Navigational Bar** will appear.
- Select > **WarmMark Shipments**.
- Create a Shipment I.D. record by populating the **Shipment I.D. column**.
- Click on the  icon, populate the field then select **Save**.

Product	Sensor I.D	Shipment I.D	Shipment Condition	Sensor Image	Location	Last Scan	Time Zone	History
WarmMark	22223WTTCYAH9K	<input checked="" type="checkbox"/> --						

Shipment I.D 22223WTTCYAH9K

  Order#378HXW11

**Save** **Close**

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- Then select **Admin > Audit Log** from the navigation bar.
- Confirm the Shipment I.D. creation was captured.

Name	Section	Action	Data	Audit Date
Mason McWilliams	QRShipment	Create	SensorID: 22223WTVj9A846, ShipmentID: Order#378HW9	2024-11-04 14:13:40

**Acceptance Criteria Met:** Yes\_\_\_\_\_ No\_\_\_\_\_

- Repeat for Shipment I.D. modification as needed.

Name	Section	Action	Data	Audit Date
Mason McWilliams	QRShipment	Modify	SensorID: 22223WTVj9A846, ShipmentID: Order#378HW10	2024-11-04 14:33:29

**Acceptance Criteria Met:** Yes\_\_\_\_\_ No\_\_\_\_\_

- Repeat for Shipment I.D deletion.

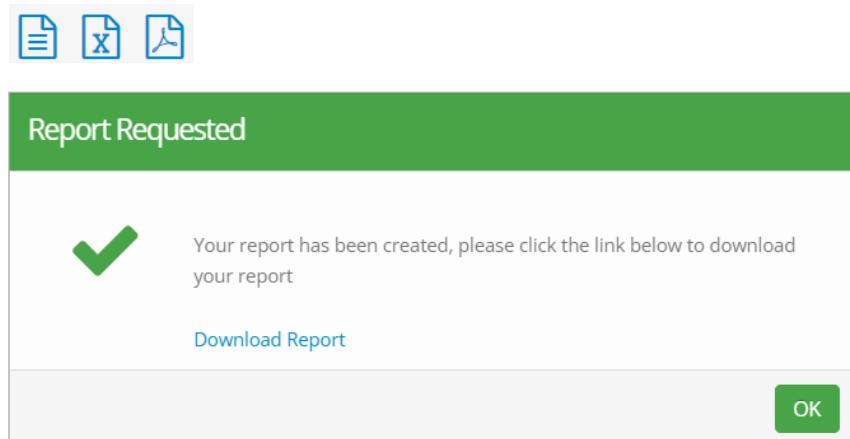
Name	Section	Action	Data	Audit Date
Mason McWilliams	QRShipment	Delete	SensorID: 22223WTVj9A846, ShipmentID:	2024-11-04 14:33:33

**Acceptance Criteria Met:** Yes\_\_\_\_\_ No\_\_\_\_\_

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### D. Exporting Records

- Position your cursor over the left side of the **Dashboard**, the **Navigational Bar** will appear.
- Select > **WarmMark Shipments**. Navigate to the Export icons and **select one**:



- Select **Download Report**, then **OK**.
- Move to the navigation bar and select **Admin > Audit Log** from the navigation bar.
- Confirm the data export was captured.

Audit Log					
User	View All	Date	2024-11-04	to	2024-11-04
10	records per page	Search			
Name	Section	Action	Data	Audit Date	
Mason McWilliams	Reporting	Create	ReportType: AuditLog, UserID: 0, Section: , Type: , DateRange: 2024-11-04 00:00:00-2024-11-04 23:59:...	2024-11-04 14:37:27	