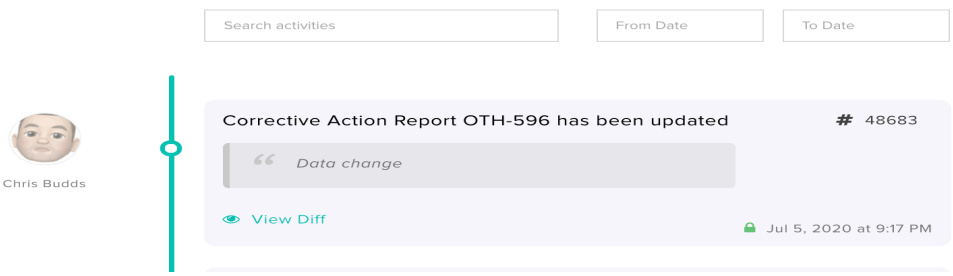
ISOLOCITY SOFTWARE VALIDATION

FDA 21 CFR Part 11 Compliance

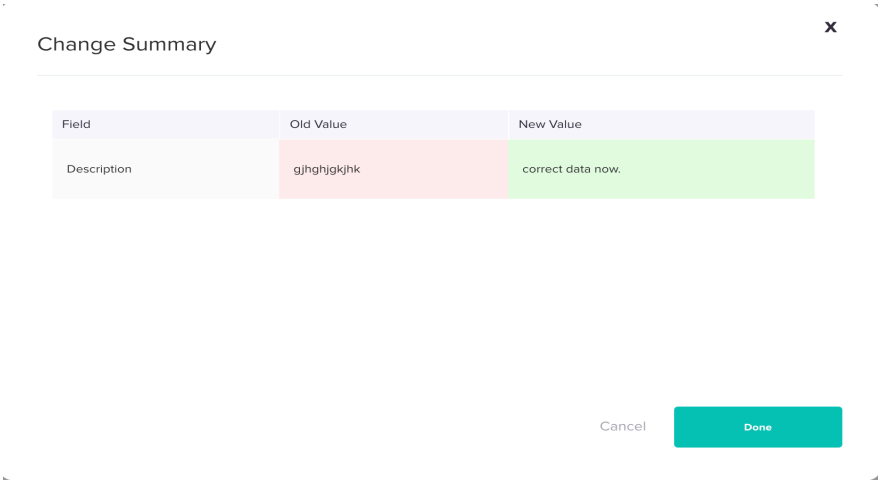
Rule Number:

11.10a - Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

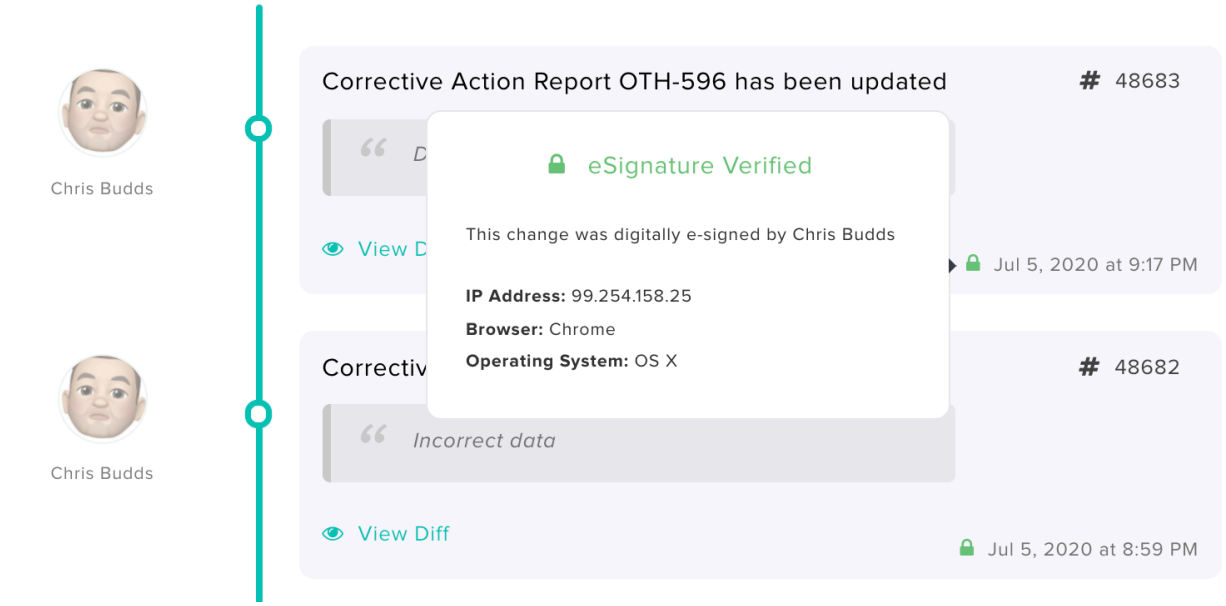
Reference Isolocity QP-11 rev 2, software verification and validation to ensure reliability, accuracy and consistent performance. Also, every form has an activity tracker that provides a ready-only content audit trail of all changes made. Ex: creation, modification, review, approval and deletion of records. It prevents any kind of records and documents alteration already approved in the system.

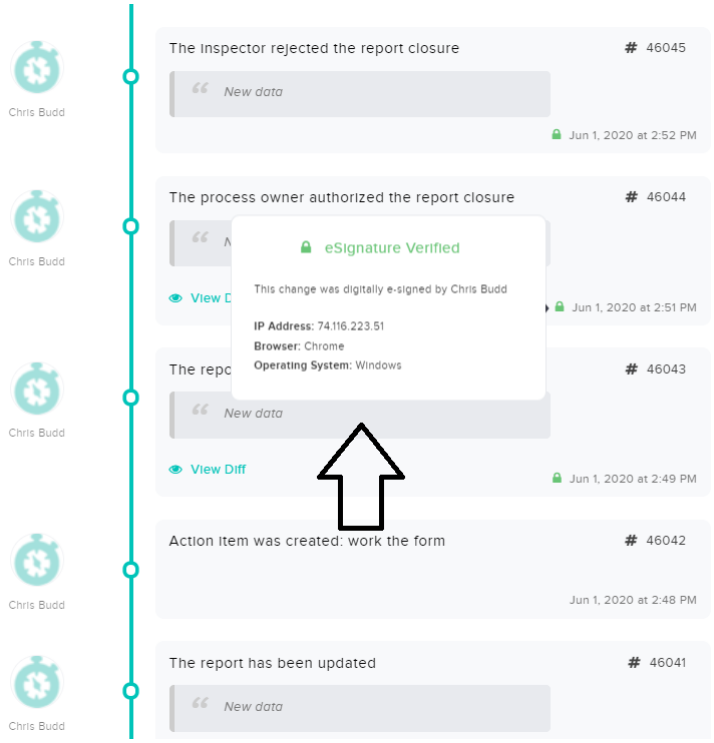


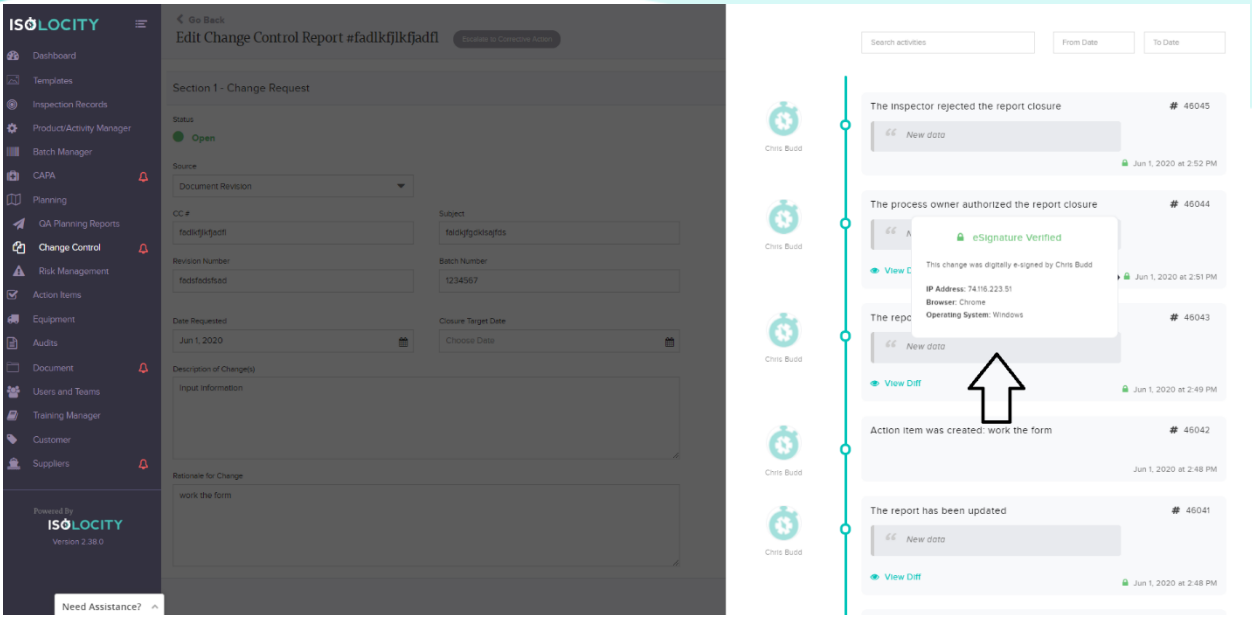
The changes to data are logged with a reason code along with e signature validation.



E-signature verified


Chris Budds
Corrective Action Report OTH-596 has been updated
48683
eSignature Verified
This change was digitally e-signed by Chris Budds
IP Address: 99.254.158.25
Browser: Chrome
Operating System: OS X
View D
Jul 5, 2020 at 9:17 PM
Chris Budds
Correctiv
48682
Incorrect data
View Diff
Jul 5, 2020 at 8:59 PM


Chris Budd
The inspector rejected the report closure
46045
New data
Jun 1, 2020 at 2:52 PM
The process owner authorized the report closure
46044
eSignature Verified
This change was digitally e-signed by Chris Budd
IP Address: 74.116.223.51
Browser: Chrome
Operating System: Windows
Jun 1, 2020 at 2:51 PM
46043
New data
View Diff
Jun 1, 2020 at 2:49 PM
Action item was created: work the form
46042
Jun 1, 2020 at 2:48 PM
The report has been updated
46041
New data



It is possible to download PDF's that provide a timestamp and expiration date.

Generated by Chris Budds on July 5th 2020, 9:05:01 pm. The document is valid until the next business date.

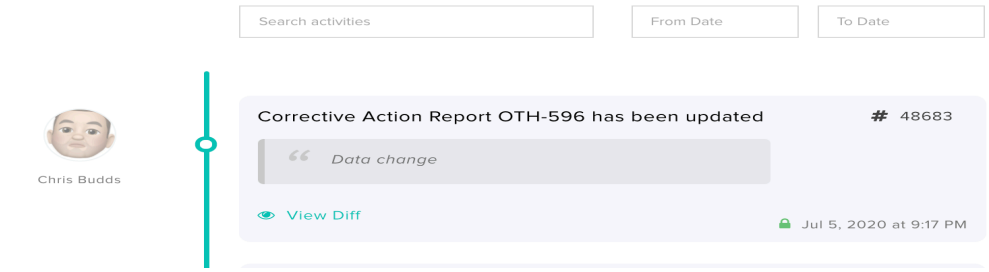
11.10b The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records

Isolocity provides archive folders for clients to store completed or obsolete data. Isolocity does not archive any data automatically, unless requested by the client.
All data provided is in in their original document format/form. It can be used for inspection/review.

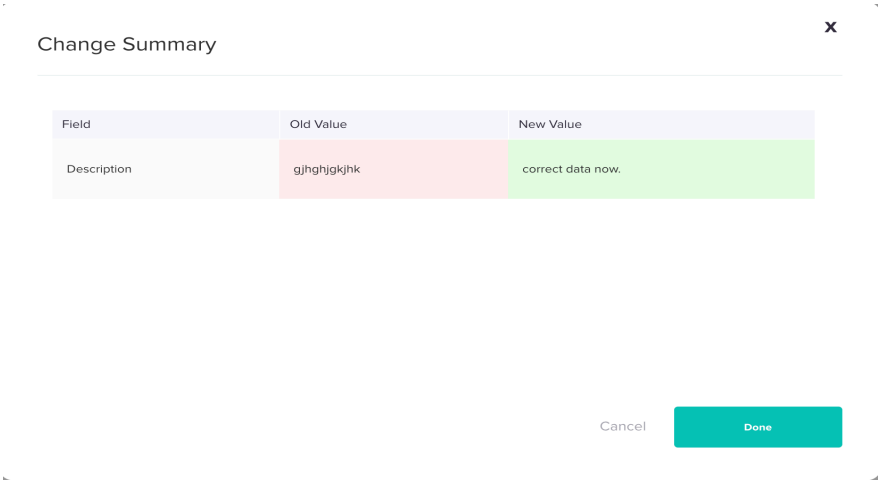
It is possible to download PDF's that provide a timestamp and expiration date.

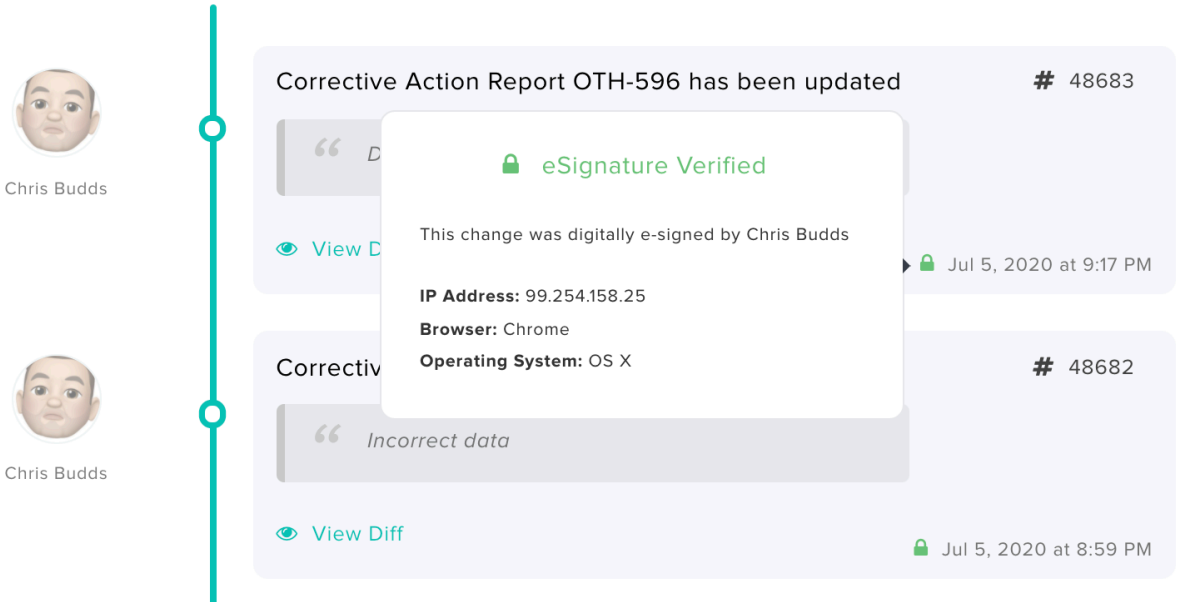
Generated by Chris Budds on July 5th 2020, 9:05:01 pm. The document is valid until the next business date.

Every form has an activity tracker that provides an audit trail of all changes made. Ex: creation, modification, review, approval and deletion of records. It prevents any kind of records and documents alteration already approved in the system.



The changes to data are logged with a reason code along with e signature validation.



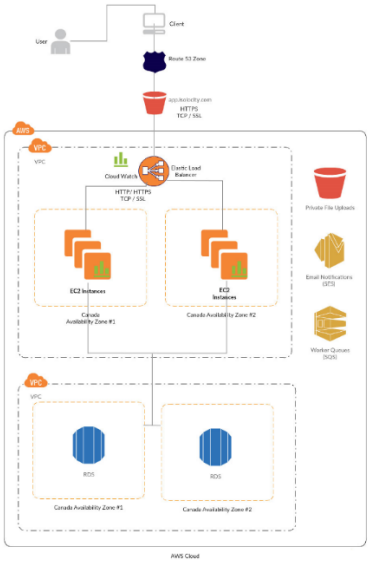


Furthermore, Isolocity allows the export of document content in CVS reports.

11.10c Protection of records to enable their accurate and ready retrieval throughout the records retention period.

AWS conducts regular backups. We verify all backup logs at regular frequencies. Furthermore, our client's databases can be exported upon request. All client data is safeguarded through the AWS security protocols. AWS certificates. https://aws.amazon.com/artifact/

All data and meta data are locked down by Isolocity software to prevent any kind of fraud. The system is designed with retrieved tools. Isolocity provides obsolete data.

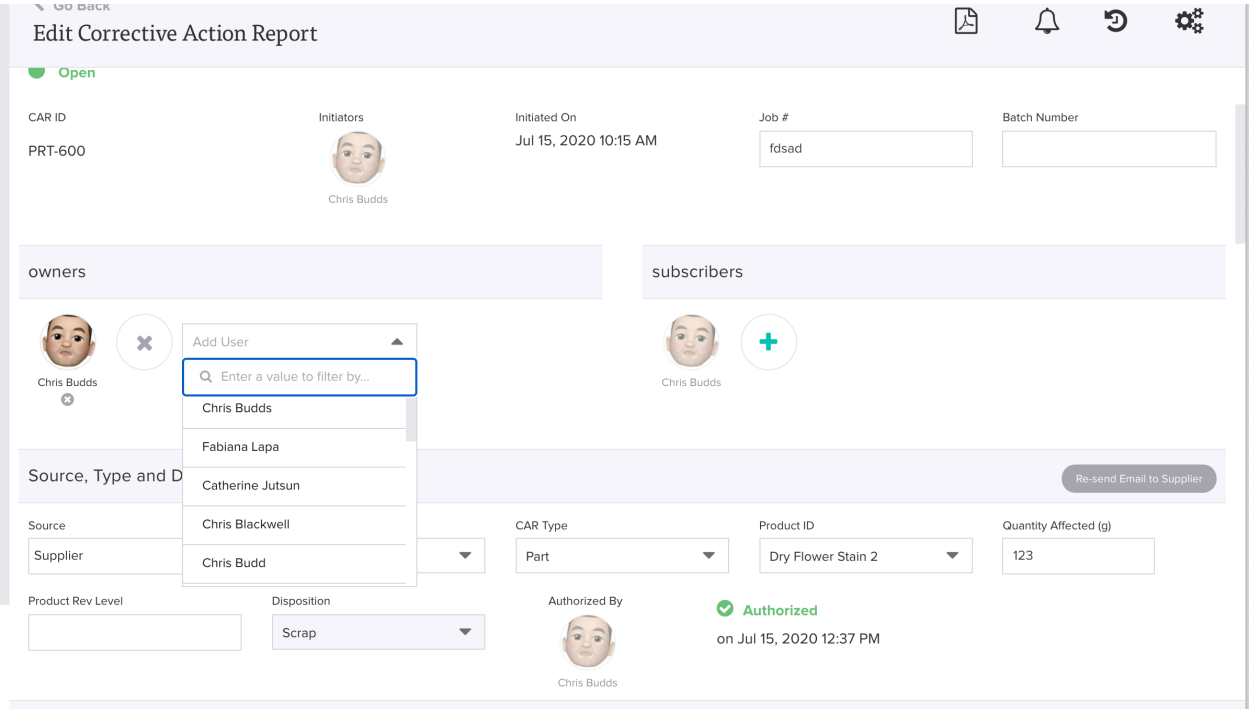


11.10d Limiting system access to authorized individuals.

Each user has his own username and password. In order to provide more security, the account will be locked after few failed login attempts. Only Isolocity system administrator can unlock an account.

Isolocity has various user tiers with data permissions. See link https://isolocity.com/user-access-permissions-qms/ Furthermore, each module and form has the ability to allocate authorized users. A user must be authorized to view and contribute to forms, if not they will not be able to view or contribute.

Electronic signatures are also required to ensure the content (approval or rejection).



11.10e Use of secure, computer-generated, timestamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying

Isolocity provides electronic signatures and a ready-only content audit trail of all changes made. Ex: creation, modification, review, approval and deletion of records. It prevents any kind of records and documents alteration already approved in the system.

It is possible to download PDF's that provide a timestamp and expiration date.

All data provided is in in their original document format/form. All data and meta data are locked down by Isolocity software to prevent any kind of fraud. The system is designed with retrieved tools. Isolocity provides obsolete data.

ISOLOCITY

Inspection #1927

Generated by Fabiana Lapa on June 29th 2020, 12:13:40 pm

Acceptance Threshold
100%

Product	Status
Blue Juice 3mg, 120 ML	Passed
Lot Serial #	Quantity Accepted
	1.00000000 units

Generated by Fabiana Lapa on June 29th 2020, 12:13:40 pm. The document is valid until the next business date.

Defect Summary

There were no defects logged for this inspection.

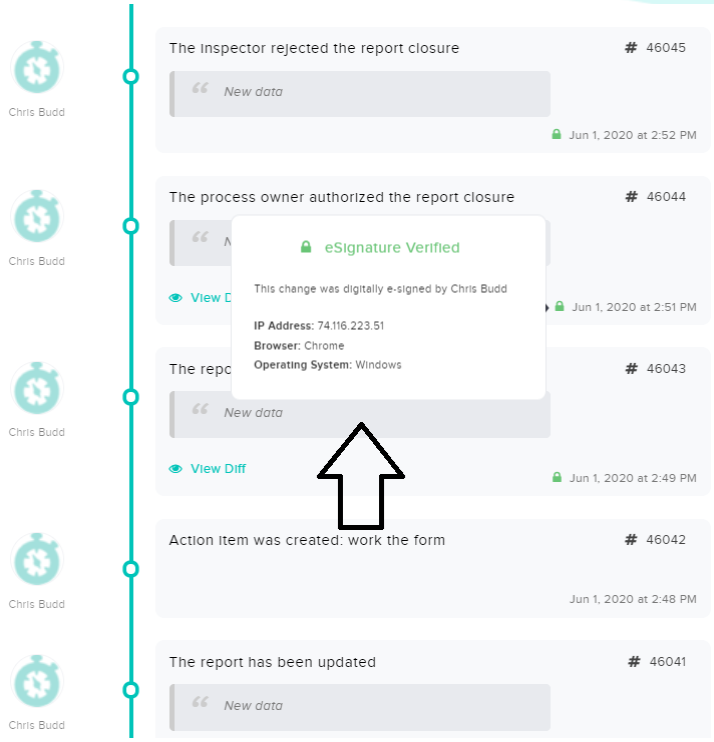
Batch Records

Blue Juice 3mg, 120 ML		
Nic	988723323	1 ml
flavouring 123	991231	120 g
Back Label		0
Bottle	22221111	1 units

Notes

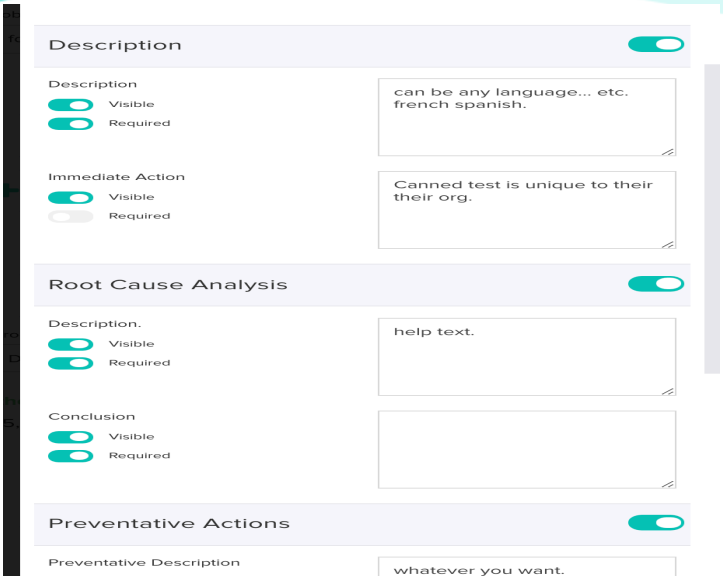
There were no notes for this inspection.

Generated by Fabiana Lapa on June 29th 2020, 12:13:40 pm. The document is valid until the next business date.



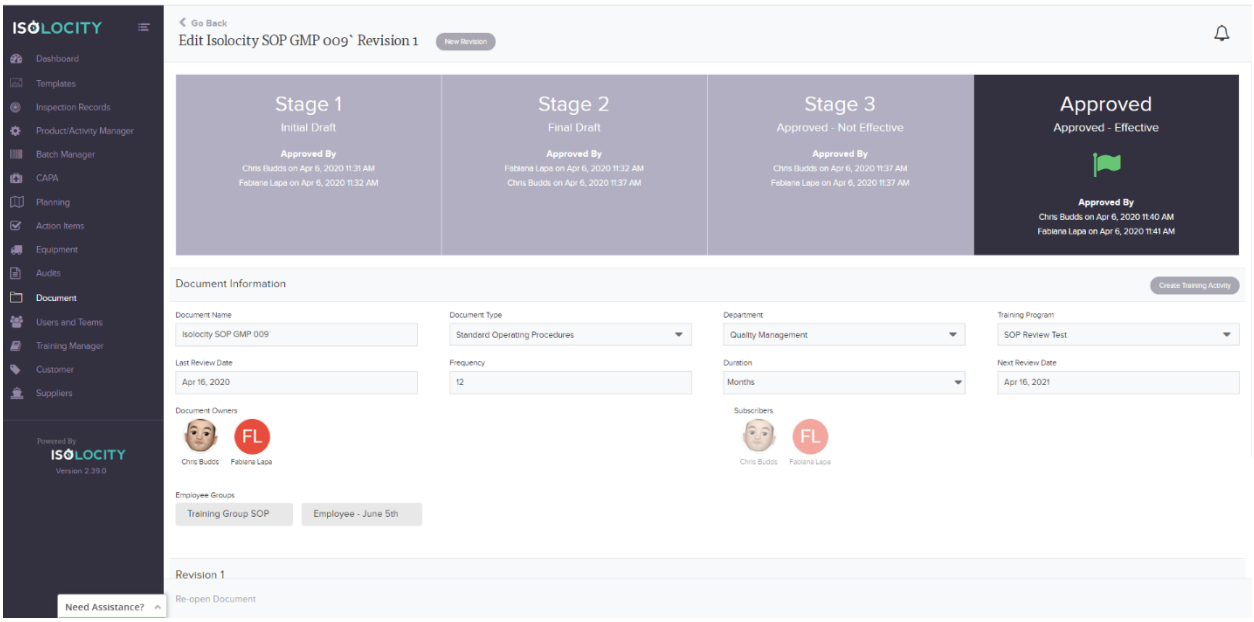
11.10f Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

All CAR, Deviations and Change Control forms have the ability to mandate various fields to be completed. See below. All user generated templates have the same ability to mandate what fields must be filled and completed prior to closing a form out.

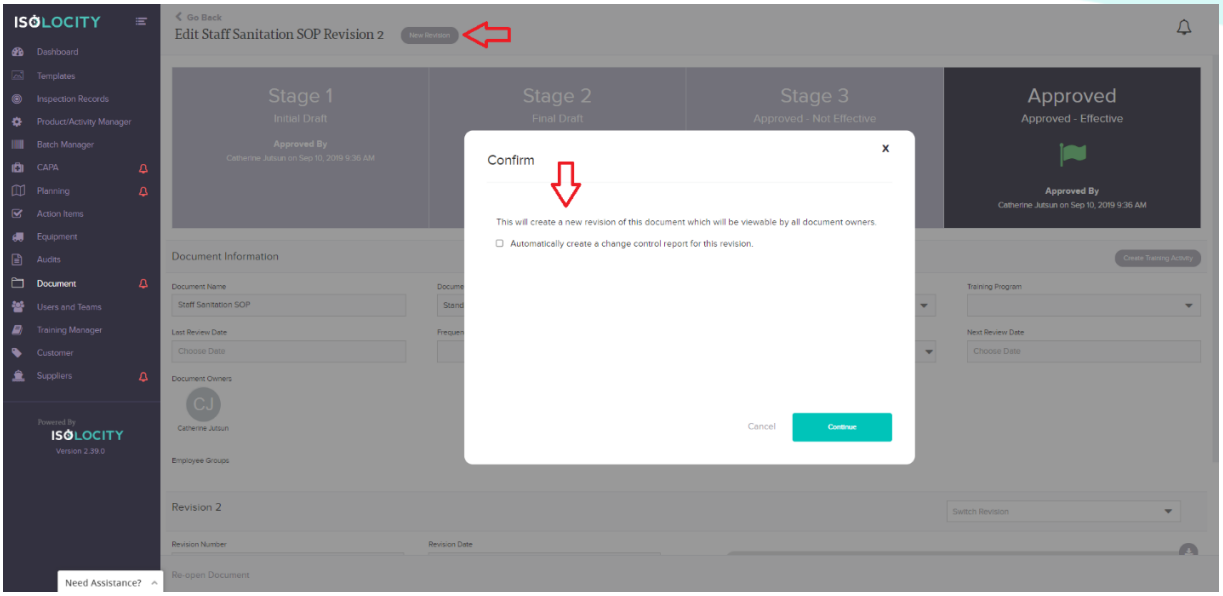


The document approval process has 4 stages (draft, final draft, approved – not effective and approved-effective).
Isolocity allows to track all new revision and achieved documents.

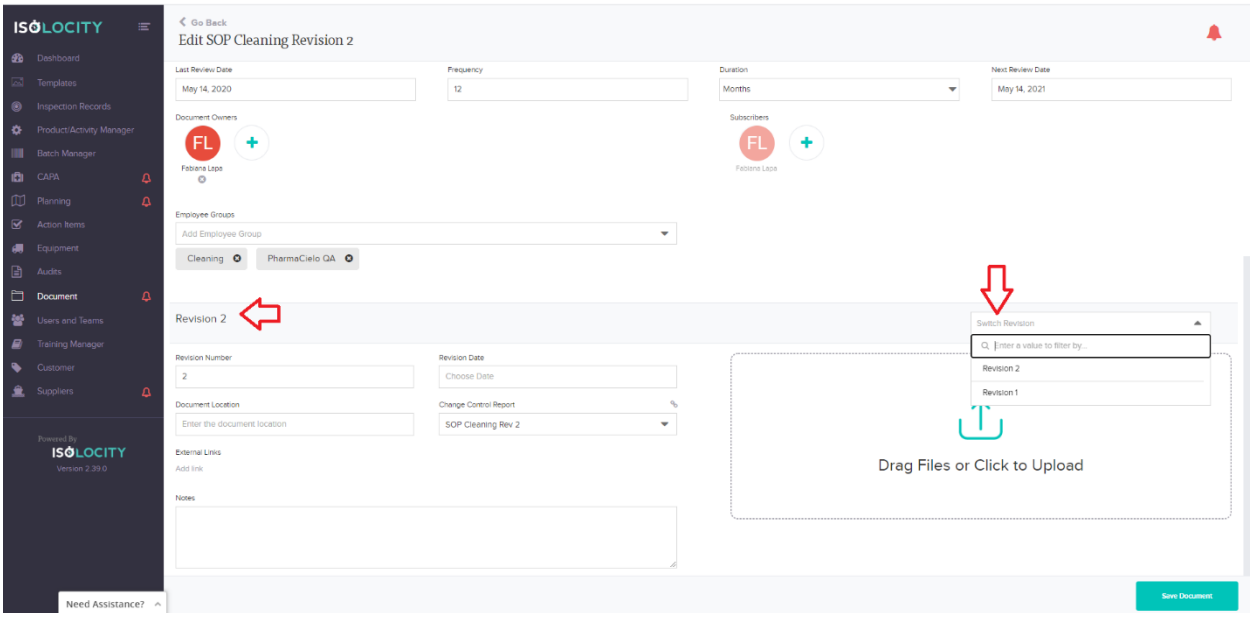
4 stages approval



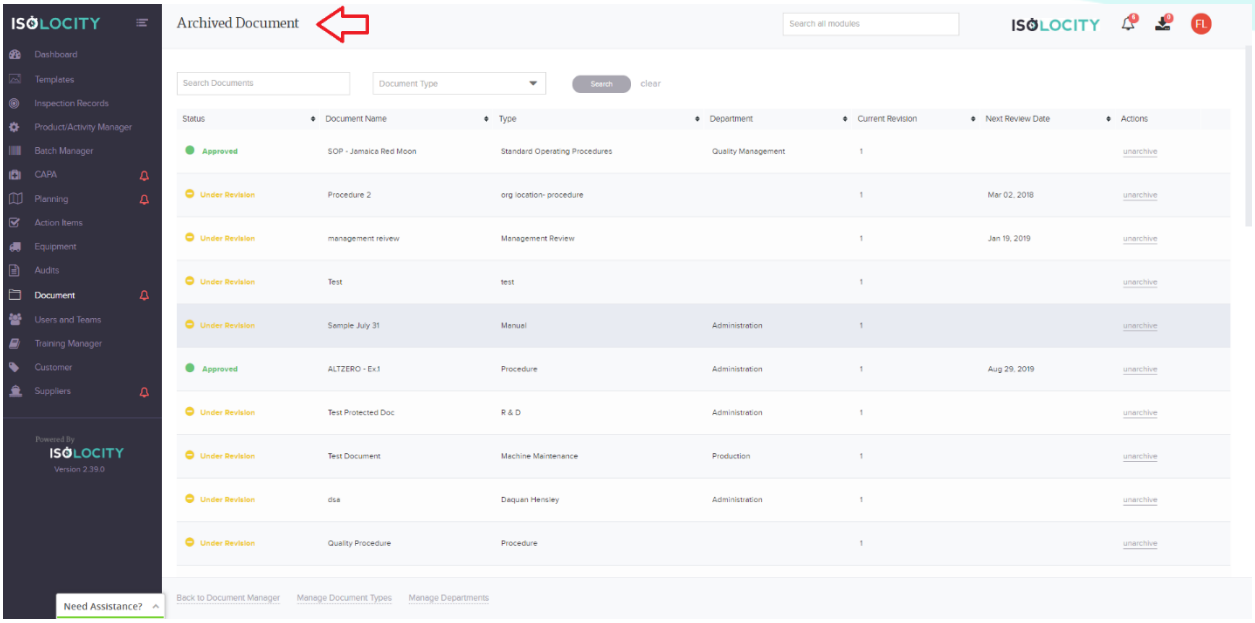
New Revision:



Track the new revisions:

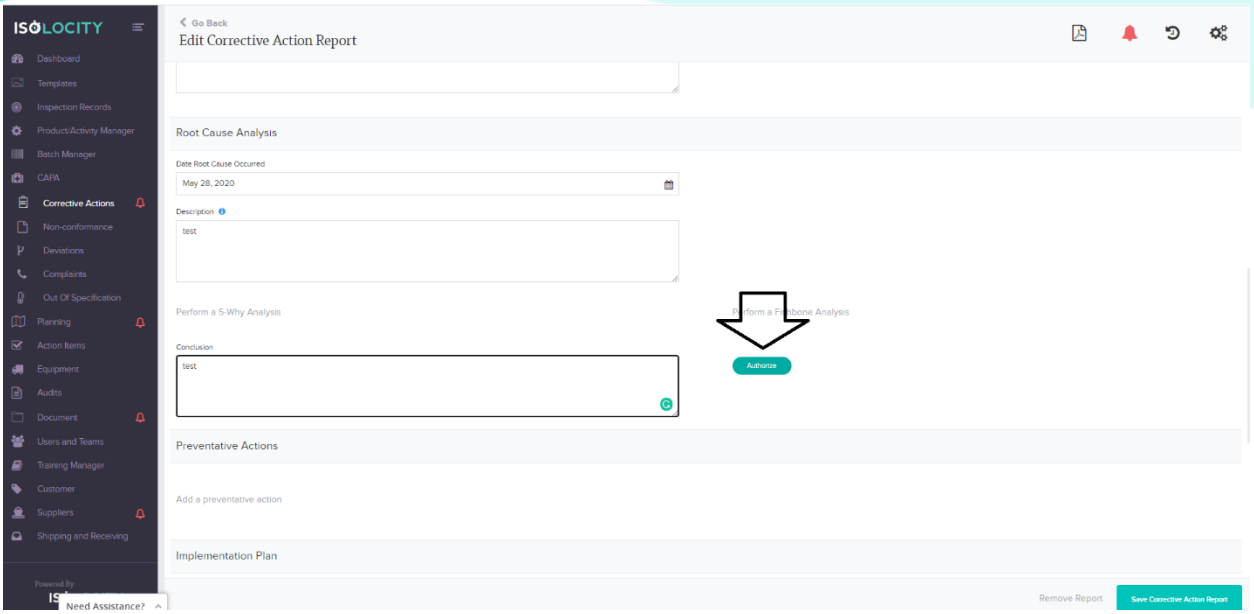


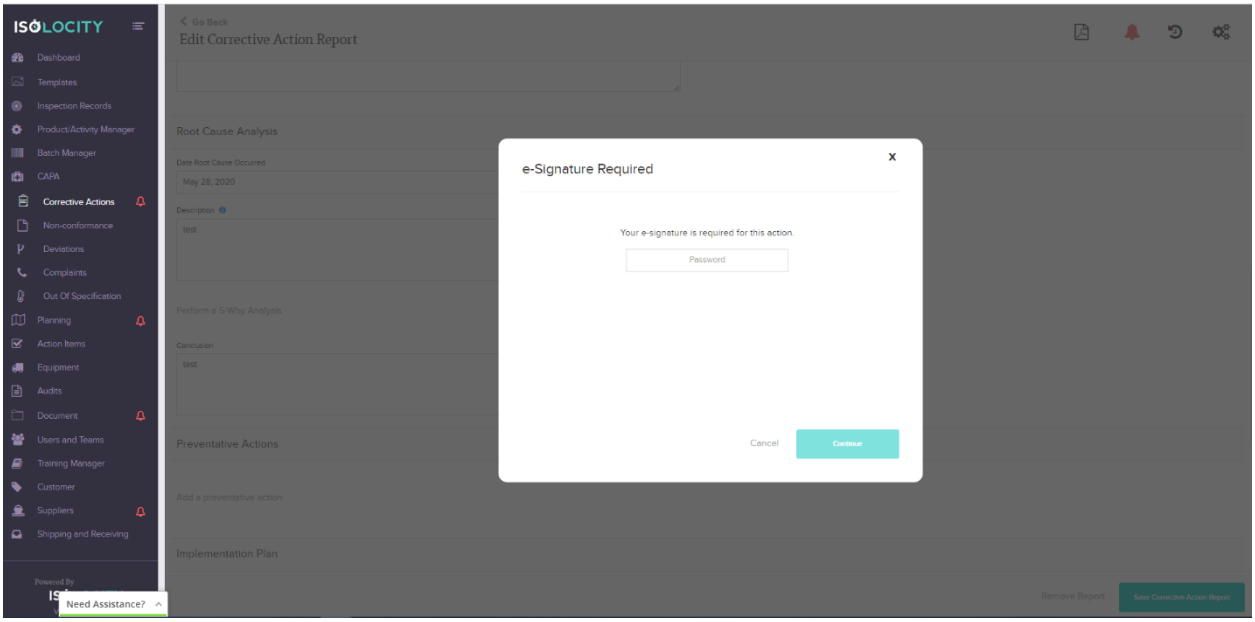
Archived Documents:

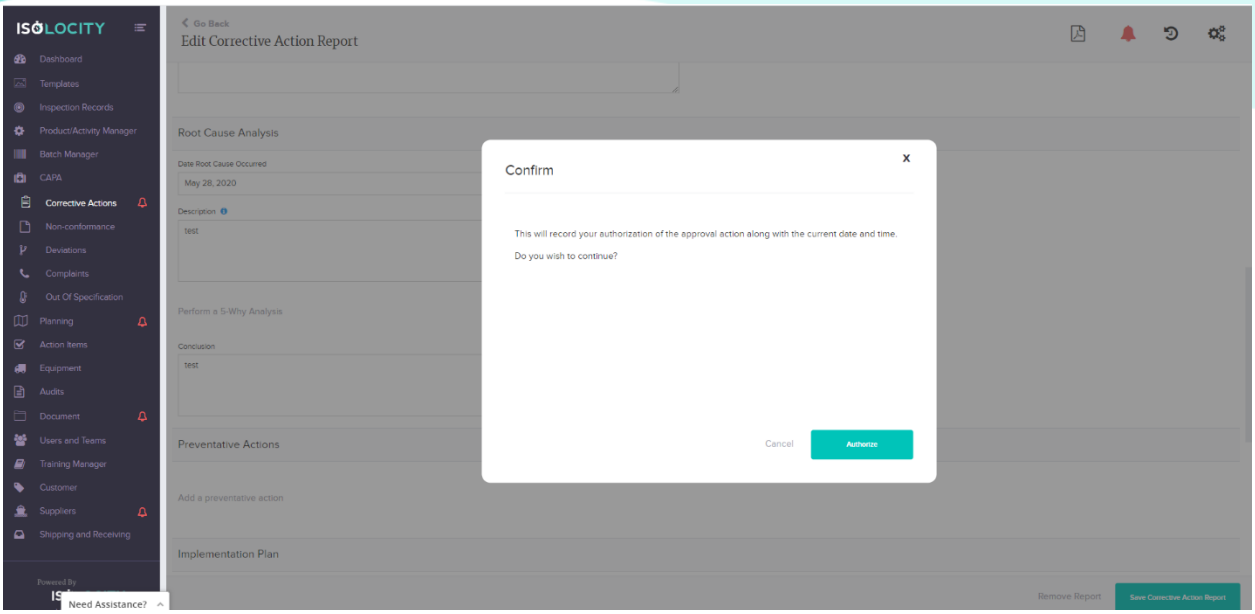


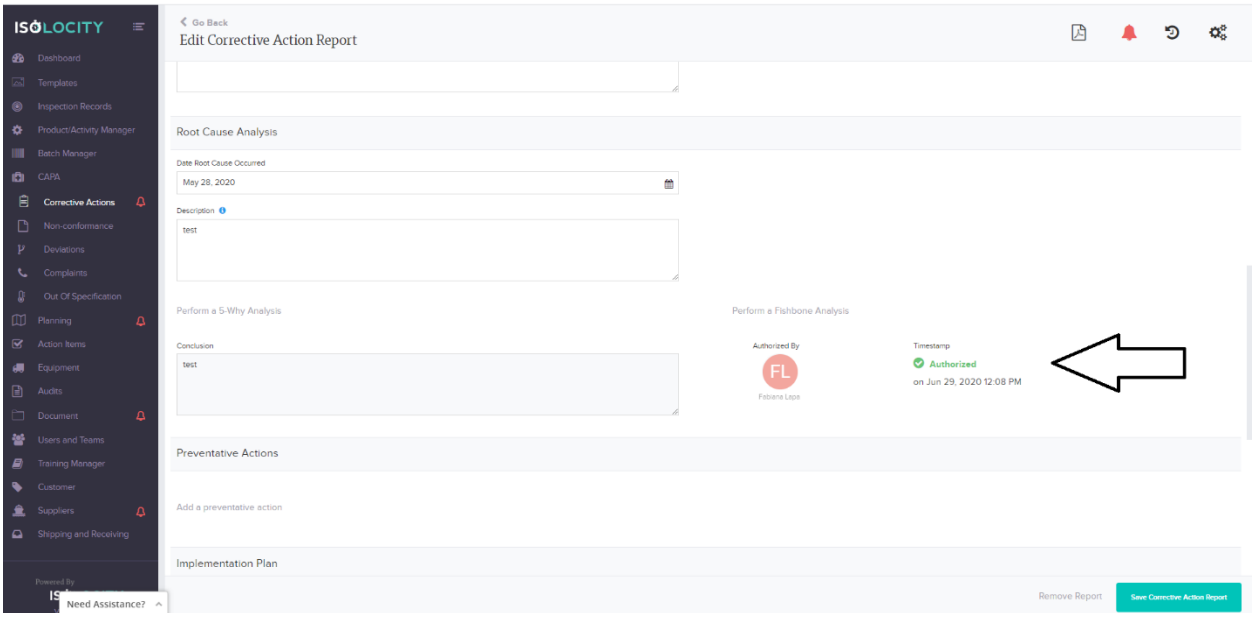
11.10g Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand

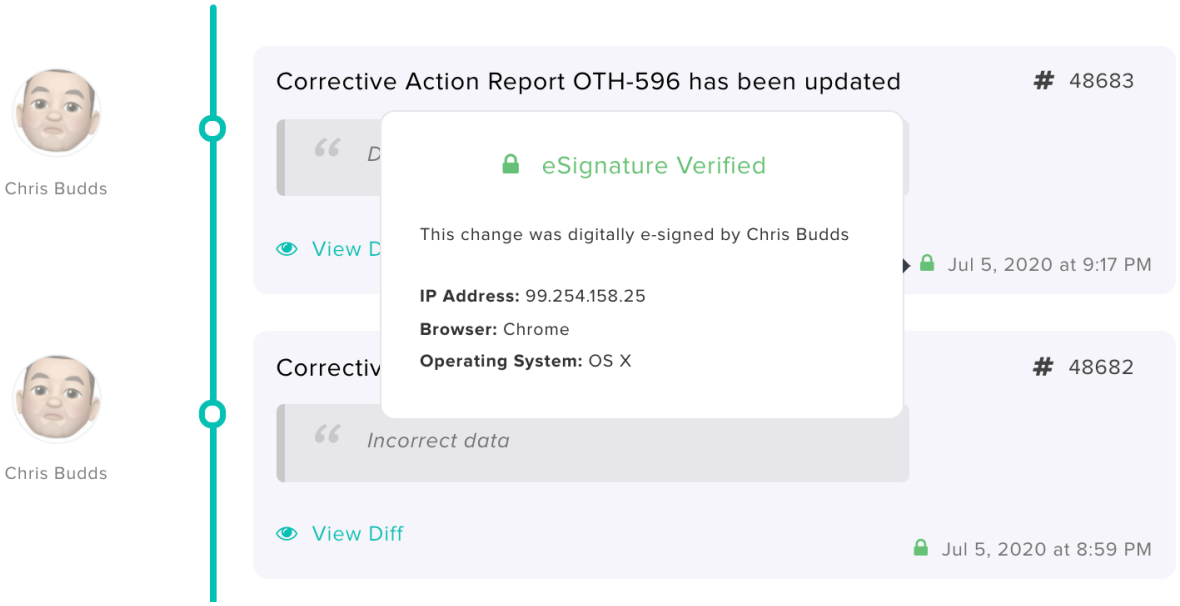
All data inputs are validated and any changes are logged and captured. Furthermore, only organization admins can reopen a closed report.
All alterations are recorded. For approved documents, it is forbidden any kind of change.
Isolocity provides electronic signatures and a ready-only content audit trail of all changes made. Ex: creation, modification, review, approval and deletion of records. It prevents any kind of records and documents alteration already approved in the system.


ISOLOCITY
Dashboard
Templates
Inspection Records
Product/Activity Manager
Batch Manager
CAPA
Corrective Actions
Non-conformance
Deviations
Complaints
Out Of Specification
Planning
Action Items
Equipment
Audits
Document
Users and Teams
Training Manager
Customer
Suppliers
Shipping and Receiving
Need Assistance?
Go Back
Edit Corrective Action Report
Root Cause Analysis
Date Root Cause Occurred
May 28, 2020
Description
test
Perform a 5-Why Analysis
Perform a Fishbone Analysis
Conclusion
test
Authorize
Preventative Actions
Add a preventative action
Implementation Plan
Remove Report
Save Corrective Action Report


ISOLOCITY
Edit Corrective Action Report
e-Signature Required
Your e-signature is required for this action.
Password
Cancel
Continue
Need Assistance?


ISOLOCITY
Go Back
Edit Corrective Action Report
Root Cause Analysis
Date Root Cause Occurred
May 28, 2020
Description
test
Perform a 5-Why Analysis
Conclusion
test
Preventative Actions
Add a preventative action
Implementation Plan
Remove Report
Save Corrective Action Report
Confirm
This will record your authorization of the approval action along with the current date and time.
Do you wish to continue?
Cancel
Authorize
Need Assistance?


ISOLOCITY
Go Back
Edit Corrective Action Report
Root Cause Analysis
Date Root Cause Occurred
May 28, 2020
Description
test
Perform a 5-Why Analysis
Perform a Fishbone Analysis
Conclusion
test
Authorized By
FL
Timestamp
Authorized
on Jun 29, 2020 12:08 PM
Preventative Actions
Add a preventative action
Implementation Plan
Remove Report
Save Corrective Action Report
Need Assistance?

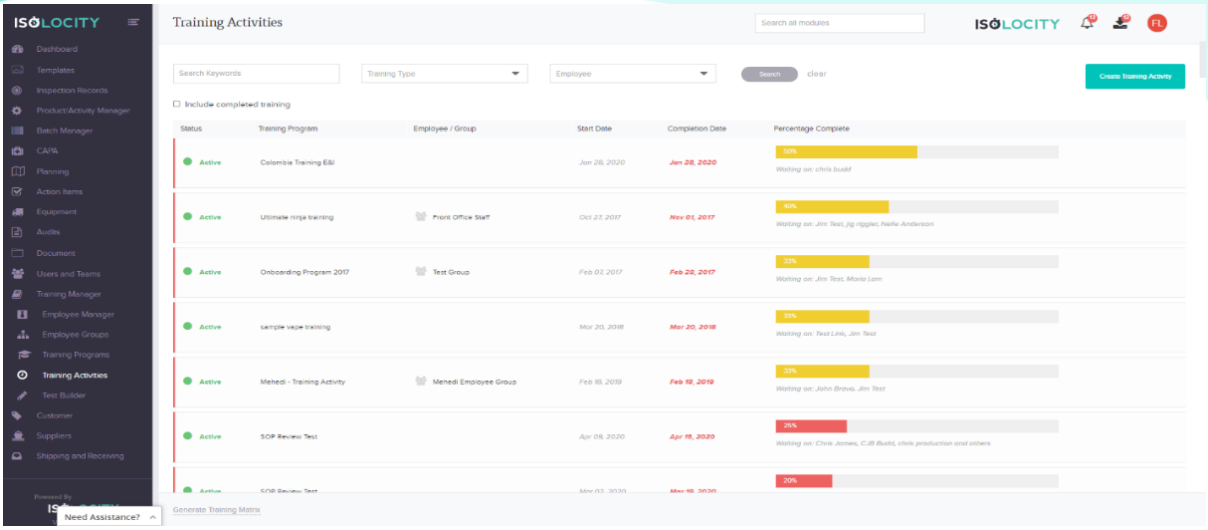


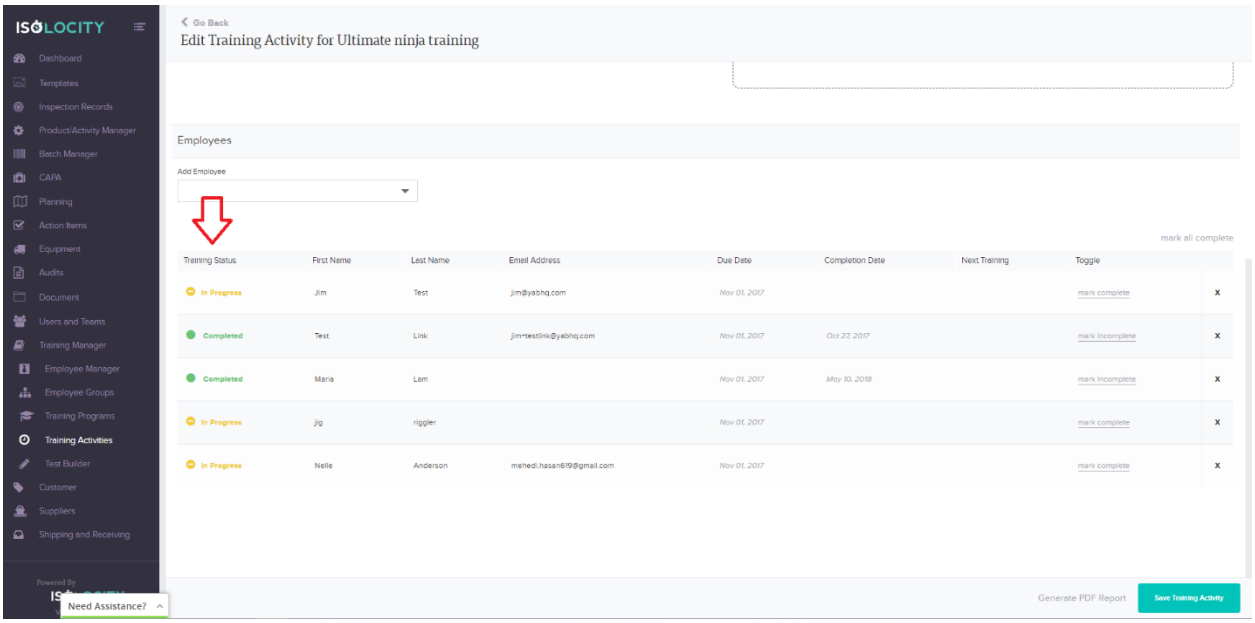
11.10h Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

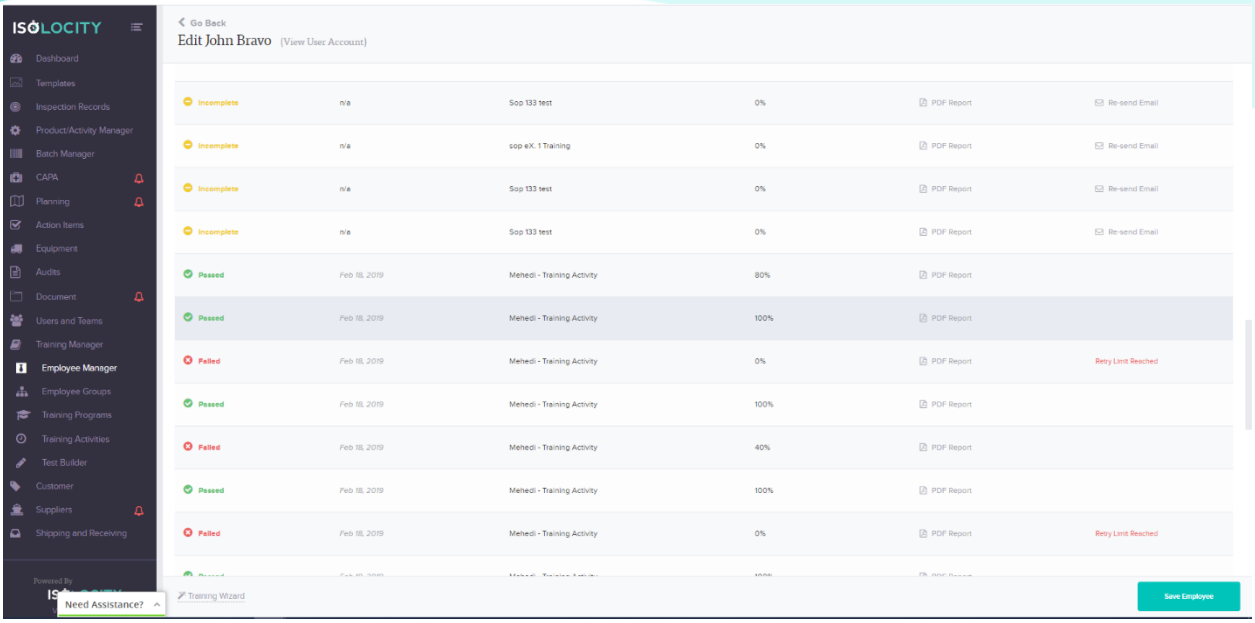
Not Applicable to Isolocity.

11.10i Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

Isolocity training manager can we setup to drive document training and other competency training events. The system can be used to schedule training, refresher training and training that are linked to documents and tests. All test scores and kept in the employee profile and are viewable (ready-only) by manager level access.

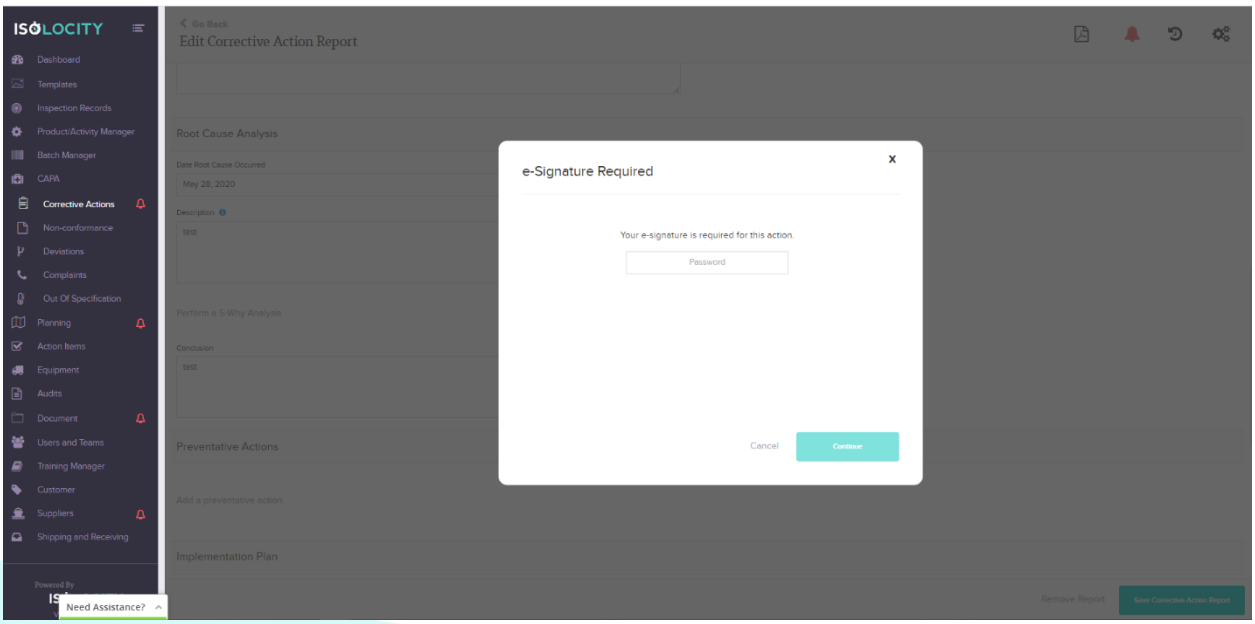

Training Activities
Search all modules
Search Keywords
Training Type
Employee
Search
clear
Create Training Activity
Include completed training
Status
Training Program
Employee / Group
Start Date
Completion Date
Percentage Complete
Active
Colombia Training E&I
Ultimate ninja training
Front Office Staff
Onboarding Program 2017
Test Group
Mehedi - Training Activity
Mehedi Employee Group
SOP Review Test
Need Assistance?
Generate Training Matrix


Go Back
Edit Training Activity for Ultimate ninja training
Employees
Add Employee
mark all complete
Training Status
First Name
Last Name
Email Address
Due Date
Completion Date
Next Training
Toggle
In Progress
Completed
Need Assistance?
Generate PDF Report
Save Training Activity



11.10j The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

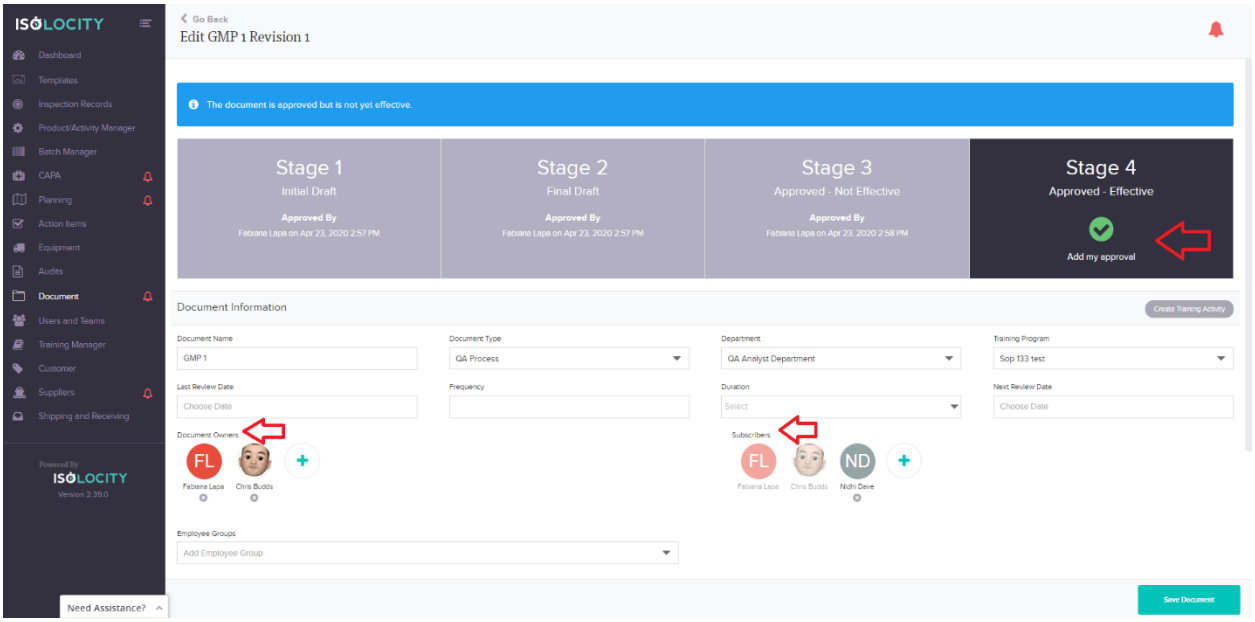
Client driven process. Isolocity mandates password validation prior to any inputs or changes being acceptable.
Tests, quizzes or checklists can be applied in the training program module to ensure user comprehension.

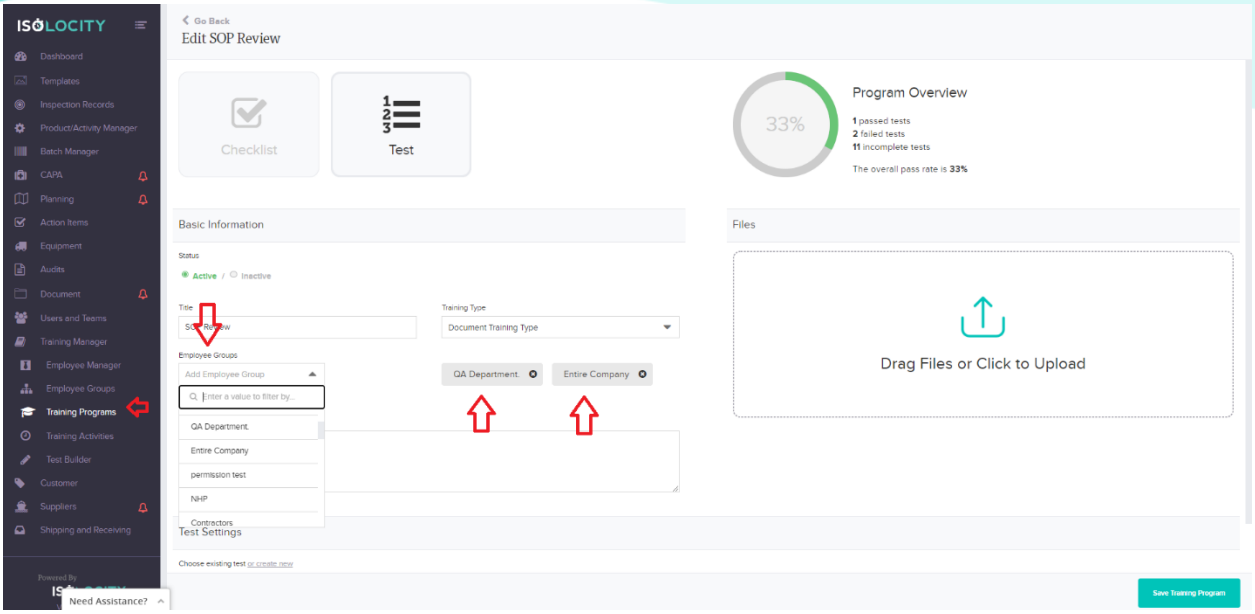


11.10k Use of appropriate controls over systems documentation including: 1. Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. 2. Revision and change control procedures to maintain an audit trail that documents time sequenced development and modication of systems documentation.

1. Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

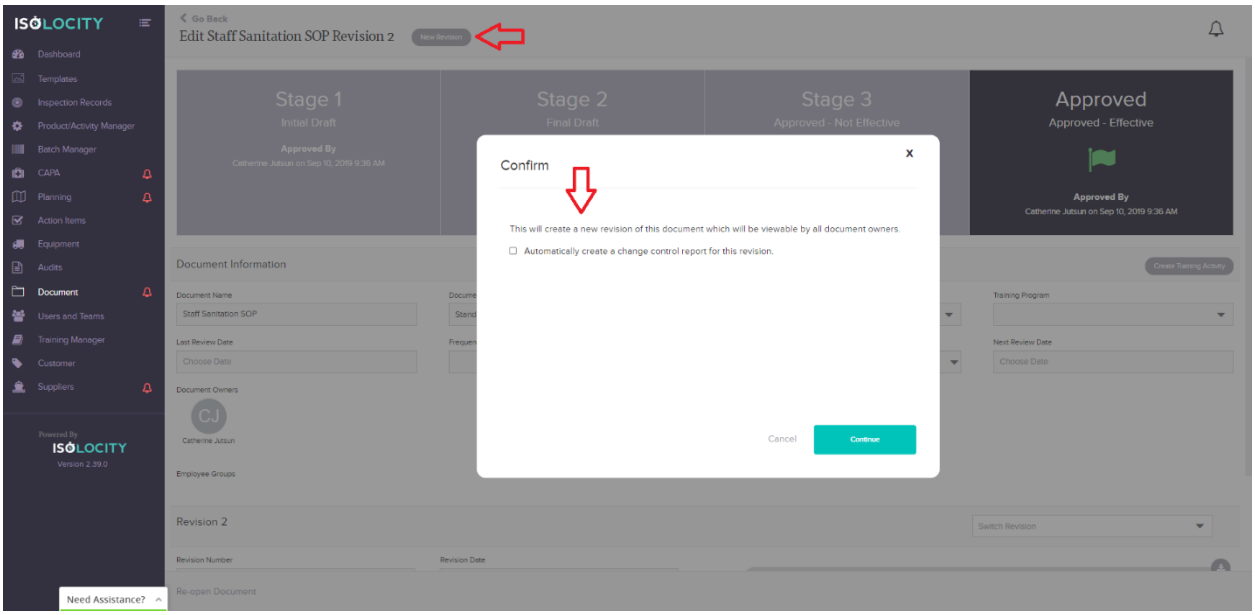
PDF format prevents any kind of alteration (ready-only). Distribution is a client process.
All users have its own login and password.
Also, every form has an activity tracker that provides a ready-only content audit trail of all changes made. Ex: creation, modification, review, approval and deletion of records. It prevents any kind of records and documents alteration already approved in the system.

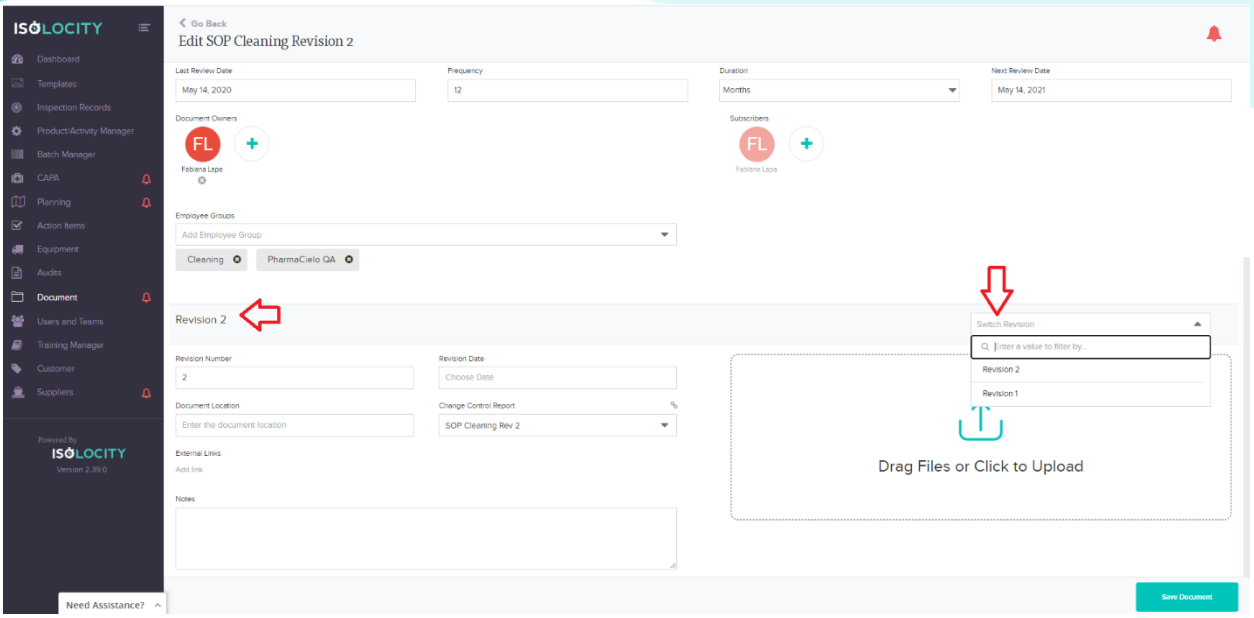




2. Revision and change control procedures to maintain an audit trail that documents time sequenced development and modification of systems documentation.

For each new revision, Isolocity allows to create a new change control report. Isolocity keeps all the previous revisions.

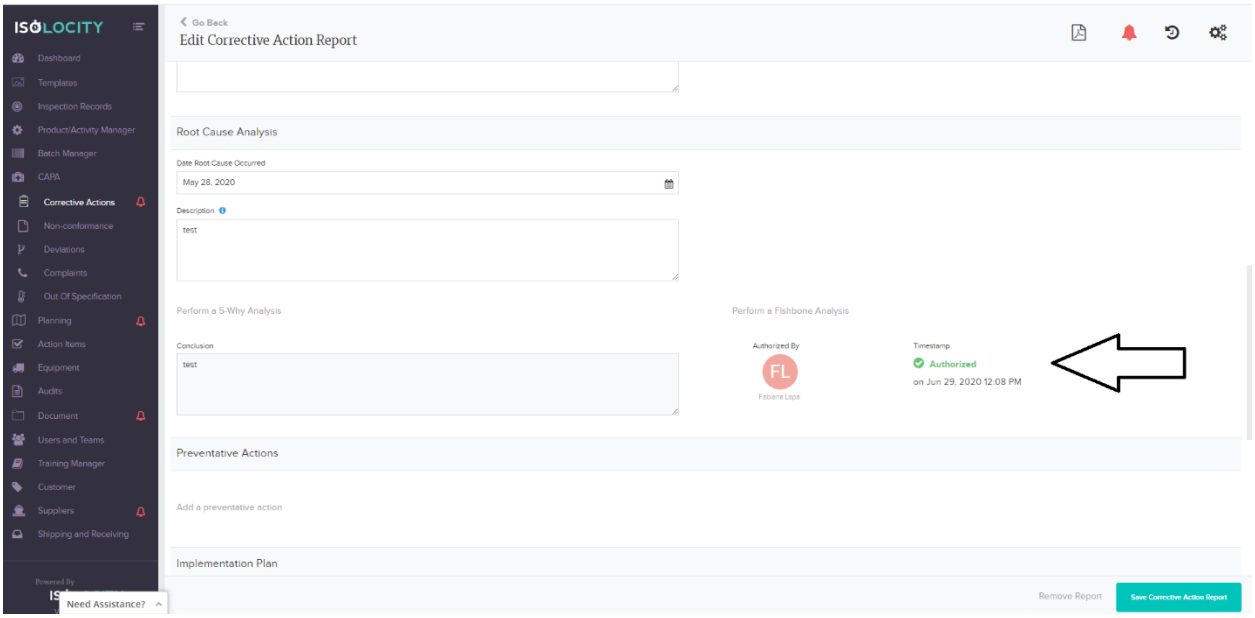


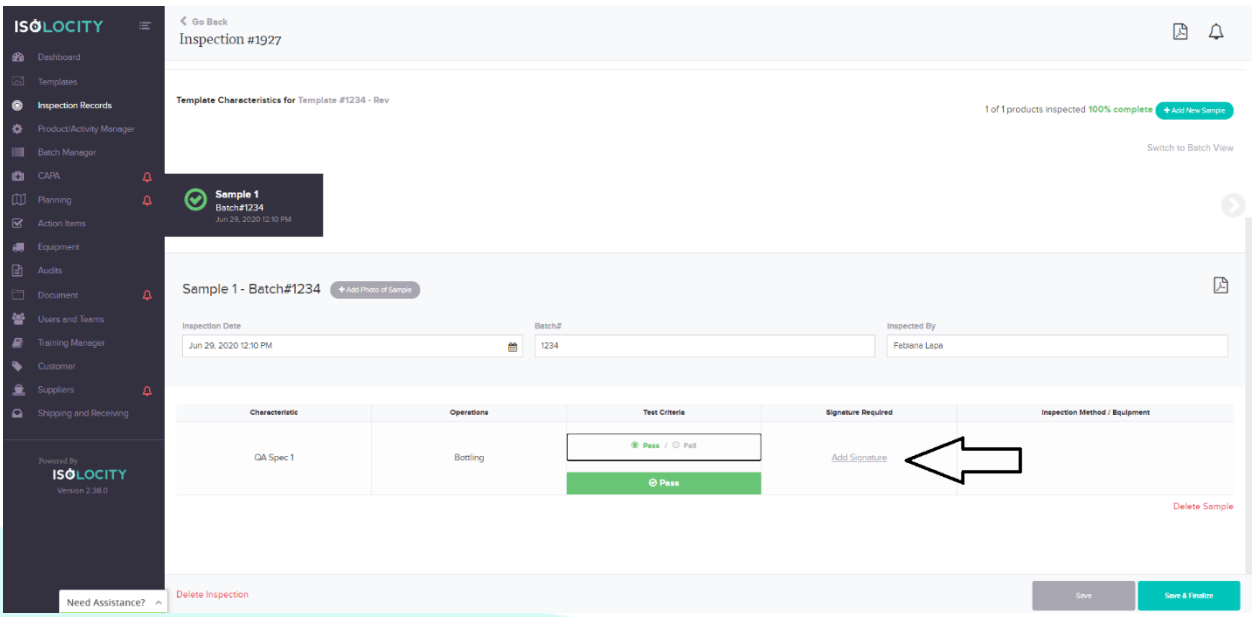

ISOLOCITY
Go Back
Edit SOP Cleaning Revision 2
Last Review Date
May 14, 2020
Frequency
12
Duration
Months
Next Review Date
May 14, 2021
Document Owners
Subscribers
Employee Groups
Add Employee Group
Cleaning
PharmaCielo QA
Revision 2
Switch Revision
Revision 2
Revision 1
Revision Number
2
Revision Date
Choose Date
Document Location
Enter the document location
Change Control Report
SOP Cleaning Rev 2
External Links
Add link
Notes
Drag Files or Click to Upload
Need Assistance?
Save Document

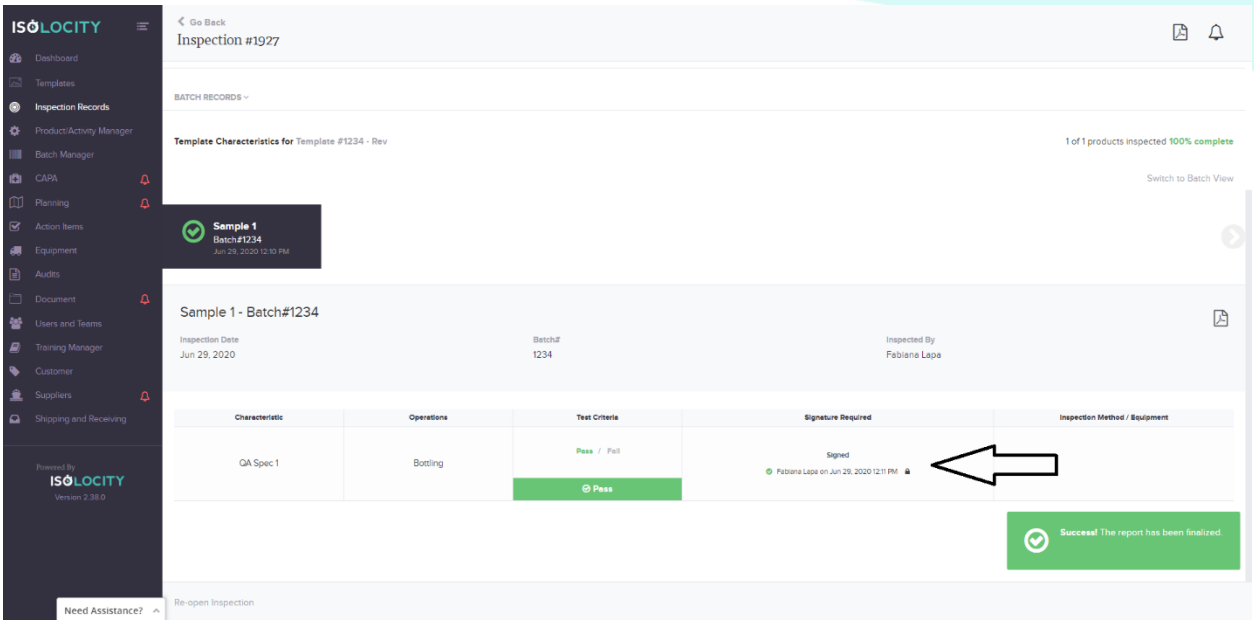
ISOLOCITY
Edit Large PDF 1 Revision 3
Revision 3
Need Assistance?
2 / 205
ISOLOCITY
A Detailed Validation Plan
Table of contents (TOC)
Table of contents (TOC) 1
Document History 4
Related Documents 4
Regression Plan 4
Purpose 4

11.50a Signed electronic records shall contain information associated with the signing that clearly indicates all of the following: 1. The printed name of the signer; 2. The date and time when the signature was executed; and, 3. The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

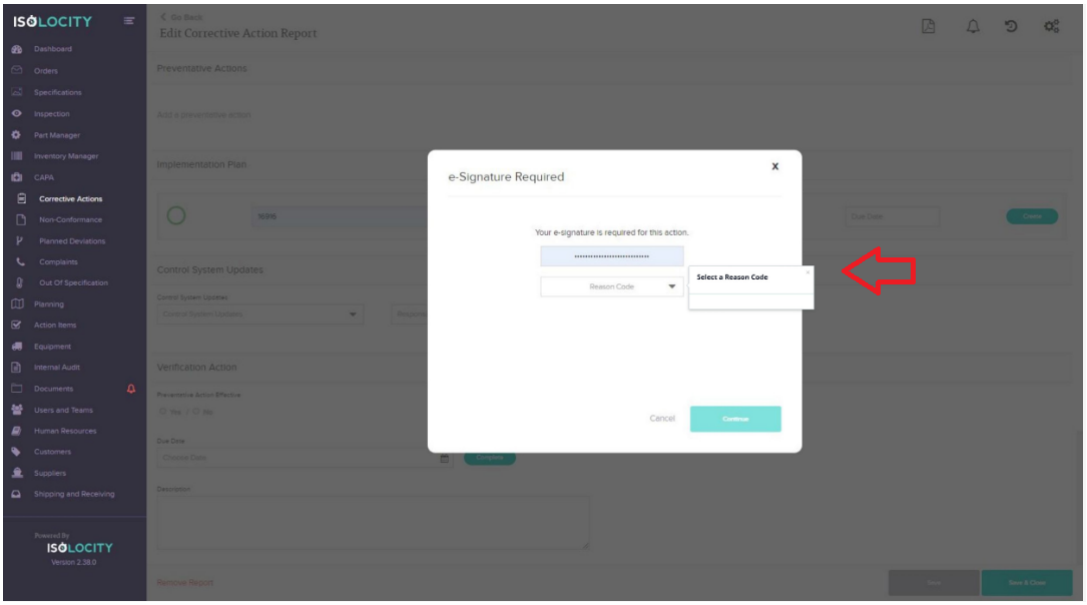
Electronic signature shows date and time. This information is tracked by the audit trails as any action taken.





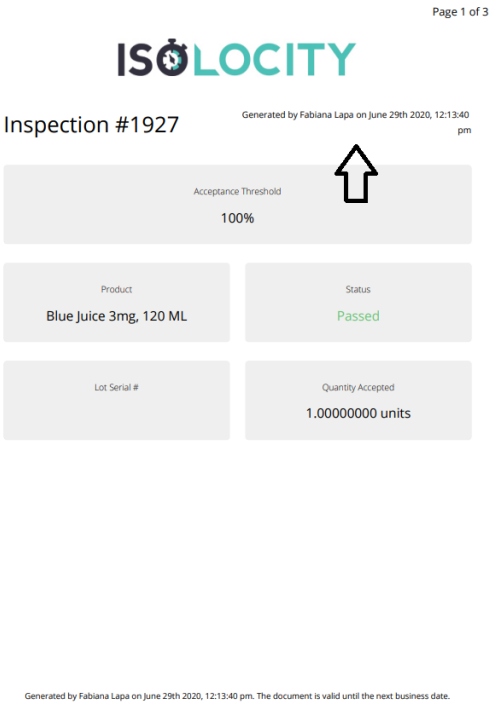

ISOLOCITY
Go Back
Inspection #1927
Dashboard
Templates
Inspection Records
Product/Activity Manager
Batch Manager
CAPA
Planning
Action Items
Equipment
Audits
Document
Users and Teams
Training Manager
Customer
Suppliers
Shipping and Receiving
BATCH RECORDS
Template Characteristics for Template #1234 - Rev
1 of 1 products inspected 100% complete
Switch to Batch View
Sample 1
Batch#1234
Jun 29, 2020 12:10 PM
Sample 1 - Batch#1234
Inspection Date
Jun 29, 2020
Batch#
1234
Inspected By
Fabiana Lapa
Characteristic
Operations
Test Criteria
Signature Required
Inspection Method / Equipment
QA Spec 1
Bottling
Pass / Fail
Pass
Signed
Fabiana Lapa on Jun 29, 2020 12:11 PM
Success! The report has been finalized.
Need Assistance?
Re-open Inspection

Reason Code:


ISOLOCITY
Edit Corrective Action Report
Preventative Actions
Implementation Plan
Control System Updates
Verification Action
e-Signature Required
Your e-signature is required for this action.
Reason Code
Select a Reason Code
Cancel
Continue

11.50b The items identied in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

PDF's reports provide full name, timestamp and expiration date.
The audit trail and recent activities can be printout.



Page 1 of 3

ISOLOCITY

Inspection #1927

Generated by Fabiana Lapa on June 29th 2020, 12:13:40 pm

Acceptance Threshold
100%

Product
Blue Juice 3mg, 120 ML

Status
Passed

Lot Serial #

Quantity Accepted
1.00000000 units

Generated by Fabiana Lapa on June 29th 2020, 12:13:40 pm. The document is valid until the next business date.

Defect Summary

There were no defects logged for this inspection.

Batch Records

Blue Juice 3mg, 120 ML		
Nic	988723323	1 ml
flavouring 123	991231	120 g
Back Label		0
Bottle	22221111	1 units

Notes

There were no notes for this inspection.

Generated by Fabiana Lapa on June 29th 2020, 12:13:40 pm. The document is valid until the next business date.

Sample #1 - 1234 Passed

Inspection Date
June 29th, 2020
12:10 pm

Inspected by
Fabiana Lapa

Inspected On
--

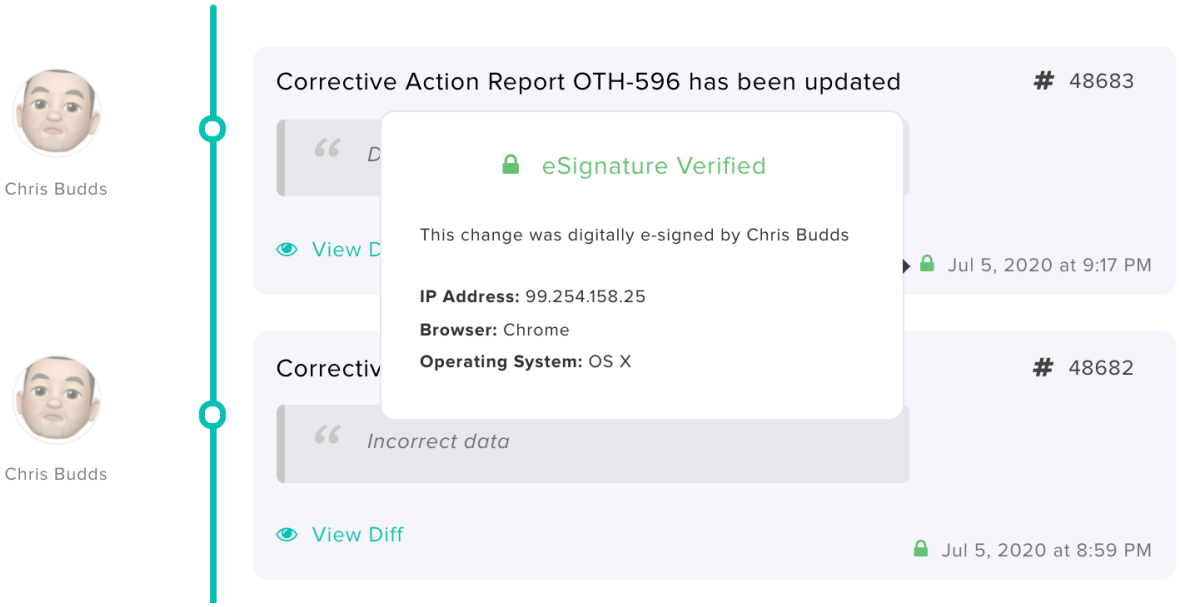
Results

Characteristic	Operation	Criteria	Value	Signatures	Method / Equipment
QA Spec 1	Bottling	(Pass/Fail)	Passed	Fabiana Lapa 2020-06-29 12:11 pm	

Generated by Fabiana Lapa on June 29th 2020, 12:13:40 pm. The document is valid until the next business date.

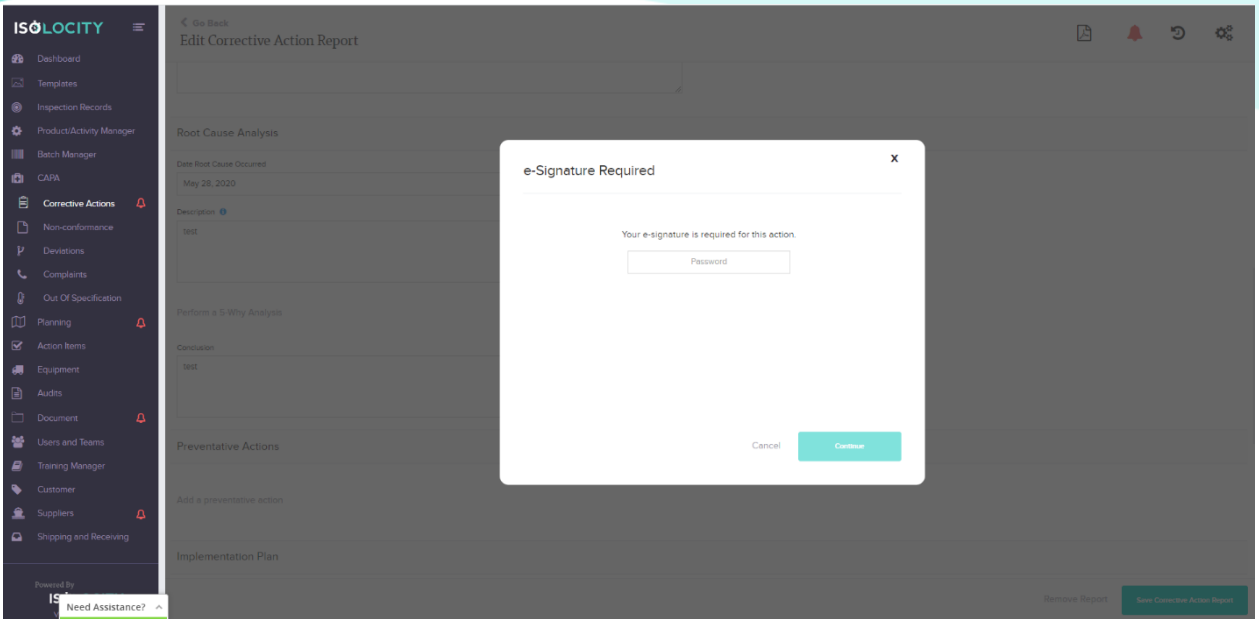
11.70 Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred so as to falsify an electronic record by ordinary means.

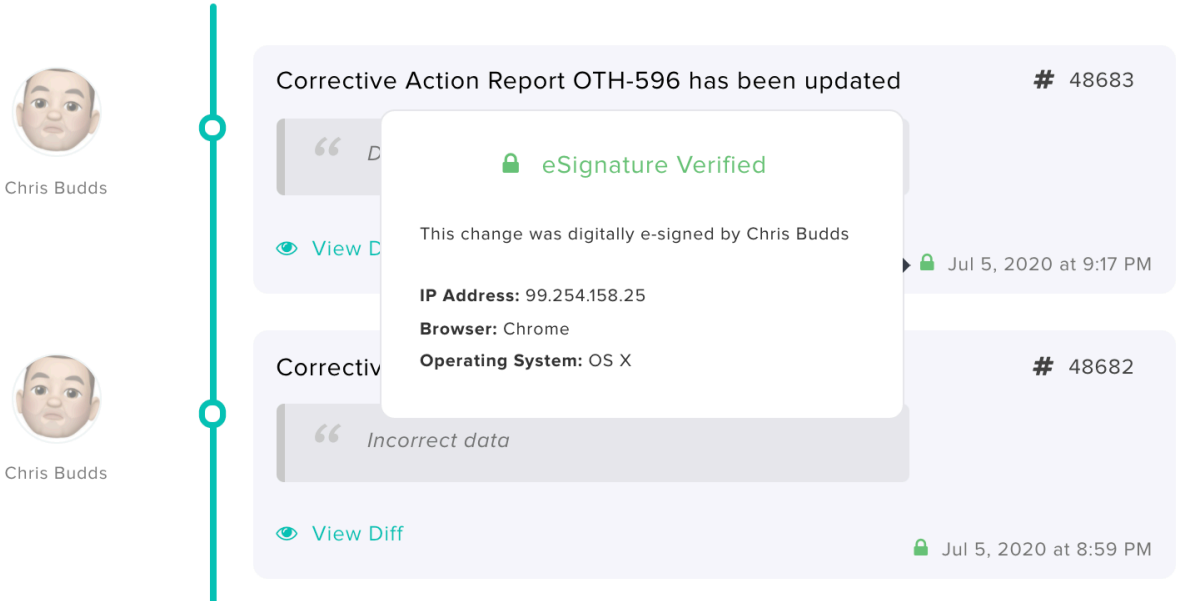
It is not possible to erase, copy or alter any electronic signature. The electronic signature can not be changed in any circumstances.



11.100a Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

Electronic signature is linked with its own account. User name and password is required. Each user has its own username and password to guarantee unique identification.
The electronic signature can not be changed in any circumstances even though a user account is inactive.



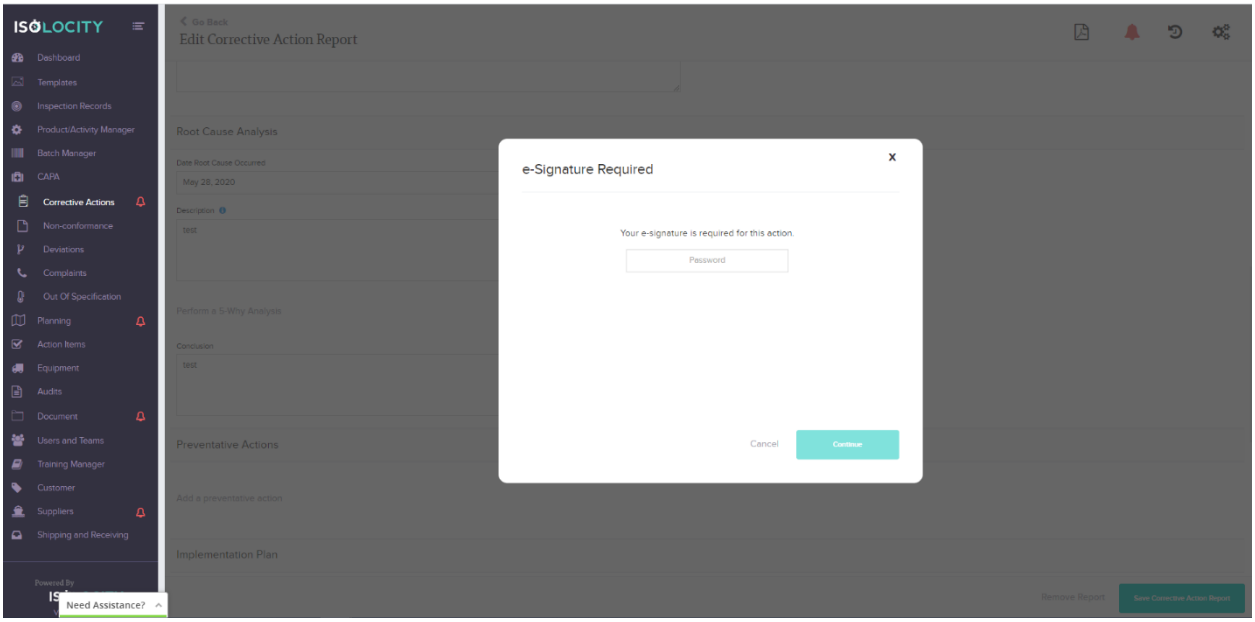


11.100b Before an organization establishes, assigns, certies or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.

This is a client's driven process.
Isolocity provides training program and training activity modules where allows the client to create tests, quizzes and checklists. Ex: Checkbox – I have read and understood the procedure/document.

11.200a Electronic signatures that are not based upon biometrics shall: 1. Employ at least two distinct identication components such as an identication code and password. 2. Be used only by their genuine owners; and 3. Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals

Isolocity requires two different identification to log in and add electronic signature: username and password which needs to be provided by the genuine owner.



11.300a Maintaining the uniqueness of each combined identication code and password, such that no two individuals have the same combination of identication code and password.

Isolocity software does not allow duplicate Usernames and passwords. Each user has his own username and password to guarantee unique identification.

11.300b Ensuring that identication code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

AWS Setup- periodic reviews can be deployed for clients.

11.300c Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

Not Applicable to Isolocity.

11.300d Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management

AWS Setup- Duel authentication can be deployed for clients.

11.300e Initial and periodic testing of devices, such as tokens or cards, that bear or generate identication code or password information to ensure that they function properly and have not been altered in an unauthorized manner

This is conducted during our validation protocols. Furthermore, out automated test suite tests these security functions.