



Quality Division Use Only

Quality Tracking #:	<input type="text" value="2022-IA-05"/>	Classification:	<input type="text" value="Incident"/>
Non-Conformance Level:	<input type="text" value="N/A"/>	Section:	<input type="text" value="Multimedia"/>
Date of Discovery:	<input type="text" value="04/01/22"/>	Date of Incident:	<input type="text" value="04/01/22"/>

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
N/A	N/A

Description of Non-conformance:
During the 2022 Multimedia internal audit the section was unable to locate the validation of the software iZotope RX5 used to process audio.

Additional Information/Follow-Up:
When reviewing the validation for iZotope RX7, approved during the internal audit scope, the document referenced the iZotope RX5 validation. The internal auditor searched for the iZotope RX5 validation in Qualtrax to complete the review but noticed that the document was not there.

The Multimedia section management was asked to provide the iZotope RX5 validation. The section manager stated that this validation was completed when HFCS was moving from the HPD building to the new building. All HFSC documents on the HPD server migrated to the HFSC server. However, it could be possible that this document was lost during the migration. The section was granted until the end of the internal audit to provide the validation to the audit team. The section manager informed the audit team that the section was unable to locate the validation.



Summary of Root Cause Analysis:

Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

N/A

Actions Taken:

The Multimedia section manager searched the iZotope RX5 validation on the Multimedia server and files where all documents migrated from HPD were kept.

The Quality Division contacted IT to ask for assistance searching the iZotope RX5 validation. IT searched for the validation in the HFSC server, migration documents and the Q:drive data that HPD provided to HFSC when the lab was separated from HPD, but the validation document was not located.

The IT Director contacted HPD IT Department to ask for assistance to locate the iZotope RX5 validation, since the validation was performed when HFSC was on the HPD server. The HPD IT Department recommended making a formal request through an IT ticket however, they made a quick search in the indexed backup data and advised that they only found references to the iZotope RX3 validation that was the previous one to iZotope RX5.

The Multimedia section manager placed an HPD IT ticket requesting a search in the HPD server for iZotope RX5 validation. HPD informed that the validation document could not be located.

Since the iZotope RX5 validation could not be located, the Multimedia section agreed to revalidate the software to have a documented validation. This validation was approved on 12/1/2022.

Section Manager: Rachel Lang

Date: 01/18/23

Division Director: Amy Castillo

Date: 01/19/23

Incidents or Corrective Actions that involve the Biology/DNA section are reviewed by the Technical Leader and CODIS Administrator.

Technical Leader: N/A

Date: N/A

CODIS Administrator: N/A

Date: N/A

Quality Director: Erika Ziemak

Date Closed: 01/19/23