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| **CAPA Report** |

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| **CAPA Number** | CAPA-040 |
| **Source** | Audit A-015: Performance Assurance ISO Audit |
| **Assignee** | Larry King |
| **Initiator** | Jacob Harris |
| **Initiated Date** | 05 Apr 2023 |

# Description

Audit A-020, ISO Stage 2 Audit, resulted in the following finding, 13029553-2.

Finding: Control of Externally Provided documents is not fully effective, or may need further definition.

Objective Evidence: Within the Test & Measurement lab, LCLS-2-HE procedures are downloaded from the Fermi Lab website and maintained in a notebook outside the document control system. Fermi Lab procedure TID-N-922 R1.4 was being referenced at the workbench to complete the piezo pigtail extension procedure.

Requirement: ISO 9001:2015 7.5.3.2, Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

# Extent of Condition

Reviewed Test & Measurement WorkCenter and found only the LCLS-2-HE project used printed procedures.

Reviewed other WorkCenters and found 5 similar notebooks of uncontrolled documents for the LCLS-2-HE project in the Cryomodule Assembly area. Each notebook contains three types of documents.

1. Blank pages for fastener sign-off are used by technicians to record fastener information and uploaded to travelers. This is acceptable and does not need correction.
2. Reference pictures of various views and cut-aways of the 3D model which are not labeled as uncontrolled or for reference only. The pictures are not intended to provide detailed technical information, rather they are used to aid the technicians in locating the bolt locations.
3. Outdated drawings of mechanical assembly which are not used by technicians and are not labeled as uncontrolled or for reference only.

# Cause

Printing controlled and uncontrolled documents for use on the production floor is a common practice. It was not fully recognized to be problematic by Group/Work Center Leads.

Additionally, the customer (SLAC) and their designated designer of record (FERMI) does not have a process to ensure new and changed controlled documents are officially transmitted to SRF OPs.

# Corrective Action

For the LCLS-2-HE Instrumentation Procedure Notebook…

1. Upload controlled versions of applicable LCLS-2-HE Instrumentation Procedures from Fermi website to the LCLS-2-HE project folder in DocuShare.
2. Add LCLS-2-HE Instrumentation Procedure collection to L2HE-RF-001 Document Register.xlsx, ensuring the existence and the location is known to the project team.
3. Revise the coversheet on the notebook to state controlled procedures are stored in DocuShare and the printed ones contained in the notebook are uncontrolled.

For the 5 LCLS-2-HE CMA Notebooks

1. Remove the drawings.
2. Create a coversheet for the collection of 3D model pictures explain they are for reference only and do not provide technical details.

# Preventative Action

1. Email to all Group/WorkCenter Leads explaining the issue described in this CAPA and its resolution.
2. Future Internal Audits of Document Management process will include sampling of Work Centers and a review of printed documents in use.

# Verification Plan

1. New coversheet of the LCLS-2-HE Instrumentation Procedure notebook.
2. Screenshot of applicable LCLS-II-HE Instrumentation Procedures uploaded to DocuShare.
3. Screenshot of L2HE-RF-001 Document Register.xlsx showing Instrumentation Procedure Collection.
4. Picture of one LCLS-2-HE CMA Notebook showing drawings have been removed.
5. New coversheet over the collection of 3D model pictures in one LCLS-2-HE CMA Notebook.
6. Copy of email to Group/WorkCenter Leads explaining the issue described in this CAPA and its resolution.

Target Completion Date: 15 Jun 2023

# Action Plan Approval

Action Plan Approval Date: <DD Mmm YYYY>, confirmed via email from Stage 2 auditor

Effectiveness Review Plan: Initiator will walk through The Test and Measurement work area and the Cryomodule Assembly area to ensure notebooks are revised as described above and that other documents are clearly labeled as controlled or uncontrolled.

Effectiveness Review Target Date: 30 Jun 2023

Note: The Effectiveness Review results are listed in SRF-13-RF-001CAPA Report Register.

# Closure

Verification Results: <Initiator describes acceptance of objective evidence listed in Section 6.>

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| **Role:** | **Name:** | **Signature:** | **Date:** |
| Assignee | Larry King |  |  |
| Initiator | Jacob Harris |  |  |
| SRF Department Head | Tony Reilly |  |  |