Attachment A

CONTROL SYSTEM ACTIVITY LOG SHEET

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Control System Activity** | | | | | |
| Type of Activity  *SOP-ES-11(D) – Disaster Recovery*  *SOP-ES-11(S) – Short Intervention*  *SOP-ES-11(T) – Engineering Test*  *SOP-ES-11(L) – Long Intervention*  *SOP-ES-11(M) – Minor Software Change* | | | Impact  *Safety*  *Quality*  *Validation* | Requirements  *Pre-approval required*  *SOP-OPS-11 Tag-out required*  *Manager-level Approvals required* | |
| **PROPOSED MODIFICATIONS FOR PREAPPROVAL**  :N/A each cell if preapproval is not required | | | | | |
| Manufacturing Area:  Click or tap here to enter manufacturing area. | | Unit Number(s):  Click or tap here to enter unit numbers. | | | |
| Control System Equipment/Software Involved:  Click or tap here to enter control system. | | | | | |
| Description of Proposed Change: (specific details required)  Click or tap here to enter text. | | | | | |
| Associated PR Number:  Click or tap here to enter PR Number. | | | | | |
| Documents to be updated: | | | | | |
| Software ID(s):  Click or tap here to enter text. | System Specification(s):  Click or tap here to enter system specifications. | | | | Drawing(s):  Click or tap here to enter drawing numbers. |

Attachment A (Continued)

| **MODIFICATIONS COMPLETED** | | | | | |
| --- | --- | --- | --- | --- | --- |
| Click or tap here to enter ES-11 number. | Date/Time of Activity:  Click or tap here to enter created date. | | | Individual Executing Activity:  Click or tap here to enter name. | |
| Control System Software/Description Involved:  Click or tap here to enter control system. | | | | | |
| Description of Issue:  Click or tap here to enter incident description. | | | | | |
| Intervention Taken:  Click or tap here to enter action taken. | | | | | |
| Root Cause:  Click or tap here to enter root cause classification. | | | | | |
| Manufacturing or Control System Lot Identifier (if product not present N/A):  Click or tap here to enter lot number. | | | | | |
| Associated PR Number:  Click or tap here to enter PR Number. | | | SOP-OPS-11 Tag-out Number:  Click or tap here to enter tag out number. | | |
| Documents Updated With Revision Numbers | | | | | |
| Software revisions created:  Click or tap here to enter software revisions. | | System Specification(s):  Click or tap here to enter system specifications. | | | Drawing(s):  Click or tap here to enter drawing. |
| Activity Completed (All activities completed, attachment routed for closure)  This attachment was initially routed on \_\_\_\_\_\_\_\_\_ | | | | | |

As-Found Conditions:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **STANDARD OPERATING PROCEDURE** | | |  |  |  |
|  |  | |  |  | | KAN-SOP-000018779 | |
| CSL BEHRING L.L.C. | | |  |  | |  | **SOP-ES-4** |
| Kankakee, Illinois | | |  |  | |  |  |
| **Engineering Support Studies** | | | | | | | |

|  |  |
| --- | --- |
| **Change Control:** |  |
| **Objective:** |  |

| **#** | **Procedure** | **Acceptance Criteria** | **Data / Result** | **Pass / Fail** | **Initial / Date** |
| --- | --- | --- | --- | --- | --- |
| ***Documentation Checks*** | | | | | |
|  | Capture screenshot or record applicable equipment or recipe statuses, such as clean or dirty states or working recipe parameters before commencement of changes. | Screenshots **are** attached. | Screenshots \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  attached. |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  | Verify PLC project. | PLC project passes Rockwell project verification **without** errors. | PLC project passes Rockwell project verification  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ errors. |  |  |
|  | Remove any testing-related simulation edits or forces from the program when testing is complete. | Simulation edits are **removed** or **N/A**.  Forces are **removed** or **N/A**. | Simulation edits are \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  Forces are \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
|  | Verify that any equipment or recipe statuses such as the clean or dirty states or working recipe parameters have been returned to their appropriate states in the program. | Equipment status settings in the program are **verified** or **N/A**.  Working recipe parameters are **verified** or **N/A**. | Equipment status settings in the program are  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  Working recipe parameters are  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |

**Comments:**

|  |
| --- |
|  |

| **Discrepancies** | | | | |
| --- | --- | --- | --- | --- |
| **#** | **Procedure #** | **Description** | **Corrective Action** | **Initial / Date** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **Instructions:**  List any discrepancies, the associated procedure numbers, a description of the discrepancy and the corrective action taken. Mark the page N/A and sign if no discrepancies exist. | | | | |

|  |
| --- |
| **Conclusions**: |
|  |