Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

CAPA Overview

CAPA Details from RIC Record

Date Opened:	08-Oct-2021 08:58 AM		
Brief Description:	Black Debris on 090010-ET Needles		
Parent ID:	343700	**Related RICs:**	PR #

CAPA Roles

CAPA Lead:	Susan Stuckwisch
CAPA Sponsor:	Ian Cage
Containment/ Correction Owner:	Will Heritch
Independent Reviewer:	Olivia Vittorio
Product/Process SME:	Tracy Waldon
Investigation Owner:	Jared Smith
Action Owner:	Jared Smith
VoE Owner:	Jared Smith

Additional Investigation Roles

Row #	Investigation Role	Investigation Role - Person

Investigation Plan

Section 1 - Problem Definition

Tools Used:	Additional Tools	**Tools Used - Additional:**	Procedural/Process Review

Problem Definition: On 18Aug2021, department 327 FQC Spencer identified black debris present on the tips and shafts of 090010-ET needles from lot 14145506. NCR 14145506*2 was opened to document the issue. The needle/stylet assembly RM3851S was from QC2 lot 2157380.1.

Section 2 - Final Problem Statement

Final Problem Statement: On 18AUG2021 in department 327, FQC Spencer, black debris was found on tips and shafts of 99 090010-ET needles.

Section 3 - Define the Investigation Scope

In Scope: Needles that are washed in Departments 50 and 60.

Out of Scope: Needles that are not washed in Departments 50 and 60.

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Section 4 - Measure and Baseline Performance

Problem Measeurement: The problem is measured by the rate of debris related nonconforming product identified post-cleaning process.

Baseline Performance: In AUG2021, 117 DCHN and 090010(-ET) needles were confirmed to have black debris foreign matter. 357370 needles were manufactured in that month which equates to an occurrence rate of 0.033%.

Section 5 - Define Data Sources Planned for Investigation

Data Sources:
- Adverse Event Reporting
- Complaint History
- Finished Product
- Interviewing SMEs
- Manufacturing
- Nonconformance History
- Product Recall
- Risk Analysis

Data Sources - Additional:

Section 6 - Planned Root Cause Investigation Tools

Investigation Tools: 5-Whys Analysis

Investigation Tools - Addt'l:

Section 7 - Additional Comments

IP Additional Comments: N/A

Section 8 - Attachments

IP Attachments: CAPA PR344356 IP1 RC Timeline.docx

Section 9 - Performed By

Current Due Date - RC: 08-Nov-2021

Justification for RC Due Date: N/A

Investigation Performed By: Will Heritch

Investigation Performed On: 29-Oct-2021 11:29 AM

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Section 10 - Approval

IP CAPA Lead Approved By:	Susan Stuckwisch	**IP CAPA Lead Approved On:**	29-Oct-2021 11:33 AM
IP CAPA Sponsor Approved By:	Ian Cage	**IP CAPA Sponsor Approved On:**	29-Oct-2021 12:06 PM
IP Ind Reviewer Approved By:	Olivia Vittorio	**IP Ind Reviewer Approved On:**	29-Oct-2021 01:14 PM
IP CRB Eng Rep Approved By:		**IP CRB Eng Rep Approved On:**	
IP CRB Ops Rep Approved By:		**IP CRB Ops Rep Approved On:**	

Root Cause Investigation

Section 1 - Root Cause Analysis

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Root Cause Analysis: The root cause analysis consisted of a review of complaints, review of procedures/processes, and a 5-Why Analysis.

Review of Complaints:

A complaints analysis was performed for affected RPNs*. Over a 2-year period, 1 foreign matter complaint was received. It was reported as loose foreign matter in the packaging (PR ID 285845).

No nonconformance analysis was performed as it is not possible to determine the nature of the foreign matter from a foreign matter attributed nonconformance.

*See Additional comments for list of RPNs

Review of Procedures/Processes:

The first process that is performed is D00185624 (Legacy Number MI_180) Rev. 006 “Disposable Chiba Biopsy Needle And MReyeÆ Disposable Chiba Biopsy Needle”. It provides instructions for cleaning vendor ground needles. Step 4.1.1.5 states to “Clean needles according to current revision of D00181670 (MI_215). Needles cleaned in ultrasonic cleaner for 1 hour. Needles must be completely dry prior to reassembly and may be placed in the oven to complete drying. “

Procedure D00181670 (Legacy Number MI_215) Rev. 008 “Cleaning Procedure Used For Washing Disposable Needles” provides general instructions for washing needles. In the instructions section 4.0 it state that “Cannula and stylets are to be completely submerged in cleaning solution while on racks, in sponge or in a glass jar.” Products are also rinsed with process water in step 4.2 and blow dried before being put in an oven in section 4.3.

Procedure D00189797 (Legacy Number QC_781) Rev. 021 “Final Inspection For Disposable Two (Three) Part Needles” provides instruction for the quality control inspection of two and three part needles. Step 4.9 states to visually examine the bevel to ensure cleanliness. This is a level 1 inspection so for a standard lot size of 600, 13 products would be inspected per D00184652 (Legacy Number QSI29-B-05-A01) Rev. 004 “Acceptance Sampling Tables”.

Review of Work Order:

Work order SA13640314 and SA13640316 (the subassembly orders for 14145506) were examined. It showed that there was a line titled “Assemble”. This line indicates the operator signed off for completing the assembly. For this order, the assemble step is to follow MI_180 Step 4.1 instructions for Vendor Ground Needles and clean the needles. For both orders, the Assemble step was signed on the same date as the first line clearance signature. Line clearance was signed again on subsequent days. This indicates that the Assemble step was not completed on the first day like the signature indicates. Per D00178633 (Legacy Number QSI04-B-09) Rev. 003 “Data Entry”, signing off on the work order should be last step before releasing the order to the next process.

SA13640314 and SA13640314 were a paper orders but orders for RPN: DCHN-22-20.0-CUI-031203-IS have since transitioned to Electronic Work Order (EWO) system.

See CAPA PR344356 Attachment RC1 5 Why Analysis for 5 Why analysis . The 5-Why Analysis determined “The operator signed off on the cleaning before completing the process for the whole order” to be the final root cause.

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Section 2 - Root Cause Results

Root Cause Results

Row #	Root Cause ID	Root Cause Description
1	RC1	The operator signed off on the cleaning before completing the process for the whole order

Section 3 - Confirm Risk

Risk Changed?: No

Risk Details:

Section 4 - Additional Comments

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

RC Additional Comments:

This list of RPNs for the complaints analysis came from 3 sources: RPNs listed on MI_180, 0900 prefix RPNs, and RPNs acquired from an affected BOM report ran for RPNs listed on MI_180

DCHN-16-5.0;DCHN-18-10.0;DCHN-18-10.0-U;DCHN-18-15.0;DZLB-18-15.0;C-DCNL-100;DCHN-18-15.0-U;DCHN-18-15.0-U-BNS;DCHN-18-20.0;DZLB-18-20.0;PNS-100-METHODIST-062185;DCNL-200;C-DCNL-200;C-DCNLY-200;DCHN-18-20.0-U;PTCD-720-J3-103087;UTA-10.2-WCE-111293;UTA-12.0-WCE-111293;PTCD-EHIME-032194;DCHN-19UT-10.0;DCHN-19UT-15.0;DCHN-19UT-5.0;DCHN-20-10.0;DZLB-20-10.0;DCHN-20-15.0;DZLB-20-15.0;DCHN-20-15.0-U;DZLB-20-15.0-U;NPAS-120-HC-NT-U-SST;DCHN-20-20.0;DZLB-20-20.0;DCHN-20-20.0-U;DCHN-21-15.0;MPIS-501-BWH-112993;DGBS-200-IUMC-122293;MPIS-501-KWON-082694;SCIS-100-VG-022196;KCFN-6.0-18-23-RA2.5-HC-BR-072000;DCHN-21-15.0-U;MPIS-501-KWON-110493;MPIS-401-20.0-SC-UA-082900;NPAS-108-HC-NT-U-SST;DCHN-21-20.0;DCHN-22-10.0;DVSLB-102;PNS-100P-LL-121389;DMCN-6.0-20XT-20.0-CD0425;MPIS-500-NT-CHLD-A-091294;DVSLB-102-U;MPIS-501-UK-060695;DCHN-22-10.0-U;NPAS-100-NT-CHILD-042695;DCHN-22-15.0;DZLB-22-15.0;C-DZLB-22-15.0;DZLBY-22-15.0;PNS-830-ST-LUKES-052085;PNS-100A-PATEL-061986;RBD-1-KADIR-061686;GATY-1-WELLESLEY-062786;PNS-100;PNS-200;PNS-100P;PNSE-100;DVSLB-101;PNS-100-MATALON-PATEL-081384;PNS-100-BLEND-100887;NPAS-100;UCAD-7.0-30-NPAS-CARRASCO;C-VSS-4.0-18-MAYO-062387;PNS-101;PNS-200P;PNS-100-VINCENT-061788;PNS-100-HGS-022285;PNS-100-COOK-020989;PNS-100-IREDELL-B-031485;PNS-100-BENSON-121589;PNS-100-MERCY-101890;CWGE-100-TGH-040591;NPAS-101-SCHWEGAL-051192;NPAS-100-YALE-051192;PNS-850-VGH-071593;NPAS-100-WPM-113093;PNS-100-SH-010594;PNS-100-SCH-012894;NPAS-100-D'AGOSTINO-A-050393;NPAS-100-D'AGOSTINO-B-050393;NPAS-100-D'AGOSTINO-C-050393;NPAS-100-D'AGOSTINO-D-050393;NPAS-100-NT;NPAS-100-D'AGOSTINO-E-050393;NPAS-100-D'AGOSTINO-F-050393;NPAS-101-NT-UT-102494;NPAS-100-D'AGOSTINO-A-NT-UK-120594;DWOPPN-19UT-4.0-STANFORD-122094;MPIS-500-NT-CHLD-B-091294;DVSLBY-101-U;NPASW-100;NPAS-100-RB;NPAS-100-RB-NT;NPAS-100-RB-NT-ST;NPAS-100-NT-ST;JWGE-104-NT-ST-BMC-020596;PNS-100-COOK-121285;NPAS-100-RB-NT-SJH-061996;NPAS-100-RH;NPAS-100-RH-NT;RCF-8.0-18-20-RB-D'AGOSTINO;CWGE-100-PRESBYTERIAN-030183;NPASW-100-RB;DVSLB-101-U;NPAS-100-D'AGOSTINO-A-UK-112497;NPASW-100-RH;VCLN-4.0-18-SEHN-031799;NPAS-100-RH-NT-WCE-110599;NPAS-100-RH-NT-BNS;NPAS-100-RB-BNS;NPAS-100-RH-NT+;NPAS-100-RH+;NPAS-100-NT+;PNS-100+;DCHN-22-15.0-BNS;DCHN-22-15.0-U;PNS-100-CANADA-070588;NPAS-100-U;NPAS-105-U-BURKL-042397;NPAS-100-RH-NT-U;NPAS-100-RB-NT-U;NPAS-100-RH-U;NPAS-105-NT-U-BURKL-042397;NPAS-100-RH-NT-U+;NPAS-100-HC-U-SST;NPAS-100-HC-NT-U-SST;BBFS-100;DCHN-22-20.0;PTCD-NI-SET-NO-1;PTCD-NI-SET-NO-4;DZLBY-22-20.0;GCIS-2;GCIS-1;TSS-4.0-18-NEFF-060585;DVSLB-100;RBD-100;PNS-100-HERMANN-071384;DVSLB-300;RBD-100-SHEFT-071586;DCNL-300;RBD-200;JWGE-101;RBD-100-GOOD-SAMARITAN-060980;C-DCNL-300;ARCS-1200-CHIN-090188;ARCS-1400-CHIN-090188;ARCS-1600-CHIN-090188;NPAS-105;PNSE-100-WINFIELD-041483;C-DVSLB-100;DZLB-22-20.0;DVSLB-100-U;NPAS-105-RH-NT;NPAS-102-RB-NT;NPAS-105-RB-NT;NPAS-105-RH-NT+;GCIS-100-NT;DCHN-22-20.0-BNS;DCHN-22-20.0-U;NPAS-105-U;NPAS-100-HIRATA-113093;NPAS-105-NT-U;NPAS-105-RB-U;NPAS-105-RB-NT-U;NPAS-105-RH-NT-U;NPAS-105-RB-NT-U-BNS;NPAS-105-RB-NT-U+;NPAS-105-RH-NT-U+;NPAS-105-HC-NT-U-SST;DCHN-22-22.5-BNS;DCHN-22-22.5-CUI-031203-BNS;DCHN-22-25.0;DCNL-400;DVSLB-104;DCHN-22-5.0;PNS-100-DGH-083093;DCHN-22-5.0-U;DCHN-23-15.0;DZLB-23-15.0;NBNS-23-15.0;DZLBY-23-15.0;C-DZLB-23-15.0;C-DZLBY-23-15.0-NHP-013089;ZNS-10.2;DCHN-23-5.0-U;DCHN-25-15.0;DZLBY-25-15.0;C-DZLBY-25-15.0;DZLBP-25-15.0;C-DZLBP-25-15.0;DCHN-25-5.0-BNS;DCHN-25-5.0-U;IDCHN-22-10.0;IDCHN-22-15.0;DCHN-18-25.0;DCHN-18-25.0-U;DCHN-18-5.0;DZLB-18-5.0;DCHN-18-5.0-U;DCHN-19-10.0;DGBS-100;DGBS-200;DGBS-100+;DGBS-200+;DCHN-19-15.0;DGBS-100-UAB;DCHN-19-20.0;DCHN-19-5.0;DGBS-101;DGBS-100-CMC-110895;DGBS-200-CMC-110895;DCHN-19UT-20.0;DCHN-20-10.0-U;DCHN-20-25.0;DCHN-20-5.0;DZLB-20-5.0;DCHN-20-5.0-U;DCHN-20-61.5-U;TJC-201-COPE;TJC-201-COPE-WS;DCHN-21-10.0;DGBS-200-IUH-122193;DCHN-21-10.0-U;DCHN-23-10.0;DCHN-23-10.0-U;DCHN-23-15.0-U;DCHN-23-20.0;DZLB-23-20.0;DCHN-23-20.0-U;DCHN-23-5.0;DCHN-24-10.0;DCHN-24-15.0;DZLBY-24-15.0;C-DZLBY-24-15.0;C-DZLBP-24-15.0;DZLBP-24-15.0;DZLBY-24-15.0-NHP-013089;C-DZLBY-24-15.0-NHP-013089;DCHN-

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

24-20.0;DZLBY-24-20.0;DCHN-25-10.0;DCHN-25-10.0-U;DCHN-25-15.0-U;DZLB-25-15.0-U;DCHN-25-20.0;DCHN-25-5.0;DZLB-25-5.0;IDCHN-20-10.0;IDCHN-20-15.0;IDCHN-20-20.0;IDCHN-22-20.0;090001-S34;090001-PRO7;090001-S9;090000;090020;090001-S26;090070-S5;090001-S20;090031;090002;090001;090031-ET;090000-D;090010-S9-ET;090001-PRO8;090070;090001-S10;090020-S1;090001-90-NF;090010-ET;090010;090060;090060-CS;090020-ET

Section 5 - Attachments

RC Attachments: Attachment-RC1-5WhyAnalysis.pdf

Section 6 - Performed By

Current Due Date - AP:	22-Nov-2021		
Justification for AP Due Date:	N/A		
Root Cause Performed By:	Will Heritch	**Root Cause Performed On:**	08-Nov-2021 04:13 PM

Section 7 - Approval

RC CAPA Lead Approved By:	Susan Stuckwisch	**RC CAPA Lead Approved On:**	08-Nov-2021 04:46 PM
RC CAPA Sponsor Approved By:	Ian Cage	**RC CAPA Sponsor Approved On:**	08-Nov-2021 05:32 PM
RC Ind Reviewer Approved By:	Olivia Vittorio	**RC Ind Reviewer Approved On:**	08-Nov-2021 04:36 PM
RC CRB Eng Rep Approved By:		**RC CRB Eng Rep Approved On:**	
RC CRB Ops Rep Approved By:		**RC CRB Ops Rep Approved On:**	

Action Planning

Section 1 - Risk Actions

Risk Actions Grid - RA

Row #	Root Cause ID	Root Cause Description
1	RA1	Specific risk management updates will be determined on the Design Change Plan (DCP).

Section 2 - Action Scope

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Action Scope - AP: The initial issue was for needle 090010-ET. As the root cause identified that the cleaning step was missed when breaking the work order into sub-groups, actions will be preventively implemented across all needles that are washed in Departments 50 & 60. Interviews with the department personnel and File Document Text search were used to determine impacted processes.

D00181670 (MI_215 Rev008, “Cleaning Procedure Used For Washing Disposable Needles”)
D00187989 (Spec_40560 Rev006, “Procedure Used For Cleaning Reusable Needles”)
D00132171 (SI-10A Rev017, “Prolystica Ultrasonic Cleaner”)

Section 3 - Action Planning V&V

Action Planning Grid

Row #	Root Cause ID	Root Cause Description	Action ID	Action To Address Root Cause	V&V Activity
1	RC1	The operator signed off on the cleaning before completing the process for the whole order.	CA1	Cleaning process(es) will be updated to require completion in one batch so that none are missed.	Review and approval by the required reviewers of the CAPA Action Phases and Change Order review/approval will serve as the V&V activity for this action.
2	RC1	The operator signed off on the cleaning before completing the process for the whole order.	PA1	Investigate other cleaning processes across CINC to determine if similar issues could occur. If so, evaluate for implementation of actions in those areas as needed.	Review and approval by the required reviewers of the CAPA Action Phases and Change Order review/approval will serve as the V&V activity for this action.

Section 4 - Verification of Effectiveness Criteria And Plan

VoE Plan:

SAMPLING PLAN
FAR-2021-045 identified the risk of this failure mode is “Low”, which is Risk Category 2, per D00184954 (QSP29-A03 Rev003, “Confidence and/or Reliability Requirements”). Therefore, per D00186920 (QSI29-D-04 Rev004, “One-Sample Tests”), the attribute sample size for risk category 2 is 29. This sample size is required to accomplish 95% confidence interval and 90% reliability per D00184954 (QSP29-A03 Rev003, “Confidence and/or Reliability Requirements”).

METHOD
Pick 29 samples post-cleaning process from Departments 50 and 60 from 29 different lots. Select lots with work order initiation date after implementation. Samples will be examined for black foreign matter per their respective QC documents depending on RPNs selected.

ACCEPTANCE CRITERIA
For the VoE to be considered PASSING, all 29 samples must be passed without black foreign matter being present.

Section 5 - Dissemination Of Information Planning

Who Needs To Be Notified?: Notification is assessed as part of the training plan of the Change Order process.

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

How Will They Be Notified?:	Notification will be appropriately established through email, training, and implementation of Change Order(s).

Section 6 - Additional Comments

Additional Comments - AP:	N/A

Section 7 - AP Attachments

AP Attachments:

Section 8 - Performed By

Current Due Date - AI:	22-Apr-2022		
Justification for AI Due Date:	See AP1.		
Action Plan Peformed By:	Will Heritch	**Action Plan Peformed On:**	22-Nov-2021 03:30 PM

Section 9 - Approval

AP CAPA Lead Approved By:	Susan Stuckwisch	**AP CAPA Lead Approved On:**	22-Nov-2021 05:43 PM
AP CAPA Sponsor Approved By:	Ian Cage	**AP CAPA Sponsor Approved On:**	22-Nov-2021 04:35 PM
AP CRB Eng Rep Approved By:	Steve Walulik	**AP CRB Eng Rep Approved On:**	22-Nov-2021 04:39 PM
AP CRB Ops Rep Approved By:	Matt Hawkins	**AP CRB Ops Rep Approved On:**	22-Nov-2021 05:51 PM
AP Prod/Proc SME Approved By:	Tracy Waldon	**AP Prod/Proc SME Approved On:**	22-Nov-2021 03:57 PM

Action Implementation

Section 1 - Verification And Validation Of Actions

Action Planning Grid

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Row #	Action ID	Action to Address Root Cause	V&V Activity	Description of V&V Results	V&V Pass/Fail	Evidence of Implementation	Date Solution Completed
1	CA1	Cleaning process(es) will be updated to require completion in one batch so that none are missed.	Review and approval by the required reviewers of the CAPA Action Phases and Change Order review/approval will serve as the V&V activity for this action.	Approval by the required reviewers of the CAPA Action Phases, in combination with the CO approval signifies that V&V has passed.	Pass	C00138905 (Attachment AI1), effective 15FEB2022, was approved to update D00181670 to Rev. 009 and D00187989 to Rev. 008 to require that ultrasonic cleaning be completed in one batch.	15-Feb-2022
2	PA1	Investigate other cleaning processes across CINC to determine if similar issues could occur. If so, evaluate for implementation of actions in those areas as needed.	Review and approval by the required reviewers of the CAPA Action Phases and Change Order review/approval will serve as the V&V activity for this action.	Approval by the required reviewers of the CAPA Action Phases, in combination with the CO approval signifies that V&V has passed.	Pass	C00145280 (Attachment AI2), effective 08APR2022, was approved to update D00129800 to Rev. 018 to outline product handling during ultrasonic cleaning procedures.	08-Apr-2022

CAPA Action Imp Date: 08-Apr-2022

Actions Eliminate Root Cause: Yes

Actions Cover Prods/Procs: Yes

Adverse Effects To Product: No

New Risks Introduced: No

Section 2 - Dissemination of Information

Dissemination of Information: Change Orders C00138905 (effective 15FEB2022) and C00145280 (effective 08APR2022) were approved and required training was completed.

Section 3 - Status of Containment Actions

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Status of Containment Actions:	The following containment activities were performed: • CON-2021-072 investigated both known and potential nonconforming kits and placed a STOP on affected lots (Attachment CC1 and CC2). • FAR-2021-045 implemented a recall for potentially affected products that were released (Attachment CC3)*. All containment actions are closed. *NOTE: Attachments to CC3 - FAR-2021-045 can be found electronically due to their large size

Section 4 - Additional Comments

AI Additional Comments:	Original training to C00138905 for CA1 was performed as read and understand. To reinforce changes made to documentation in scope of CA1, formal retraining was conducted for MI_215 (Dept 60) and Spec_40560 (Dept 50). See AI3.

Section 5 - Attachments

AI Attachments:	PR344356_AI2_C00145280 Cover Page.pdf PR344356_AI1_C00138905 Cover Page.pdf PR344356_AI3_FormalTraining.pdf

Section 6 - Performed By

Current Due Date - VE:	03-Jun-2022		
Justification for VE Due Date:	Due date allows 1 week to wait, 1 week to select the 29 samples, then 1 month to collect the data and write up the report.		
Action Imp Performed By:	Jared Smith	**Action Imp Performed On:**	20-Apr-2022 03:16 PM

Section 7 - Approvals

AI CAPA Lead Approved By:	Susan Stuckwisch	**AI CAPA Lead Approved On:**	20-Apr-2022 04:09 PM
AI CAPA Sponsor Approved By:	Ian Cage	**AI CAPA Sponsor Approved On:**	21-Apr-2022 10:10 AM
AI Ind Reviewer Approved By:	Olivia Vittorio	**AI Ind Reviewer Approved On:**	20-Apr-2022 05:07 PM
AI CRB Eng Rep Approved By:		**AI CRB Eng Rep Approved On:**	
AI CRB Ops Rep Approved By:		**AI CRB Ops Rep Approved On:**	

Verification of Effectiveness

Section 1 - Effectiveness Check

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Effectiveness Check Desc:	SAMPLING PLAN FAR-2021-045 identified the risk of this failure mode is “Low”, which is Risk Category 2, per D00184954 (QSP29-A03 Rev003, “Confidence and/or Reliability Requirements”). Therefore, per D00186920 (QSI29-D-04 Rev004, “One-Sample Tests”), the attribute sample size for risk category 2 is 29. This sample size is required to accomplish 95% confidence interval and 90% reliability per D00184954 (QSP29-A03 Rev003, “Confidence and/or Reliability Requirements”). METHOD 29 samples were selected post-cleaning process from Departments 50 and 60 from 29 different lots. Lots were selected with work order initiation date after implementation. Samples were examined for black foreign matter per their respective QC documents depending on RPNs selected. ACCEPTANCE CRITERIA For the VoE to be considered PASSING, all 29 samples must be passed without black foreign matter being present.
Effectiveness Check Results:	The VoE is considered PASSING as all 29 samples inspected showed no visual indication of black foreign matter. See Attachment VE1.
Effectiveness Check Met:	Yes
VoE Disposition:	Close CAPA as Effective

Section 2 - Additional Comments

VE Addtional Comments:	N/A

Section 3 - Attachments

VE Attachments:	PR344356_VE1_DataSheet.pdf

Section 4 - Performed By

VoE Performed By:	Jared Smith	**VoE Performed On:**	24-May-2022 12:00 PM

Section 5 - Approvals

VE CAPA Lead Approved By:	Susan Stuckwisch	**VE CAPA Lead Approved On:**	25-May-2022 08:45 AM
VE CAPA Sponsor Approved By:	Ian Cage	**VE CAPA Sponsor Approved On:**	26-May-2022 10:04 AM
VE Ind Reviewer Approved By:	Olivia Vittorio	**VE Ind Reviewer Approved On:**	25-May-2022 09:01 AM
VE CRB Eng Rep Approved By:		**VE CRB Eng Rep Approved On:**	
VE CRB Ops Rep Approved By:		**VE CRB Ops Rep Approved On:**	

Single CAPA V2 Report

PR ID:	344356	**PR State:**	Closed - Effective
Division / Project:	Cook Inc / CAPA V2	**PR State Since:**	26-May-2022 10:06 AM
Date Created:	08-Oct-2021 08:58 AM		

Legacy Fields

Legacy Fields

IP Executive Summary:

RC Executive Summary: