

Title Corrective or Preventive Action Request Form		Calhoun Operations	
Document Identification QR-100	Revision Date 5/9/2014	Revision Number 6	Page 1 of 4

(Check one)		
CAR/PAR#: GMP IA 2021-1	CAR:	PAR:
Originator: Greg Goodman	To: Quality System Coordinator	Product <input checked="" type="checkbox"/> Process <input checked="" type="checkbox"/> System <input type="checkbox"/> Stakeholder <input type="checkbox"/>

This is a request for corrective or preventive action concerning your department. Please determine the root cause of the nonconformance or potential nonconformance and the action to be taken to ensure this will not occur or recur. This request will be closed when adequate corrective action has been implemented and determined to be effective.

FACTS CONCERNING NONCONFORMANCE

Objective Evidence (Finding):

During 2021 GMP internal audit, reviewed procedure 3.5 Personnel Hygiene. Document hasn't been reviewed since 2016.

Immediate Corrective/Preventive Action (Include actual or anticipated completion date.):

None.

Responsible Person: **Mike Yoder**

Date: 10/6/2021

Question	Response
Why hasn't 3.5 procedure been updated?	#1. Internal Audit did not review procedure.
Why?	#2.
Why?	#3.
Why?	#4.
Why?	#5.
Why?	Root Cause: Document not reviewed yearly for updates.

(Include customer, material, product, course number, procedure, instruction, etc. as applicable)

ISO 22716 Standard):

see attach standard requirements below>

C/PAR issued by: Greg Goodman

Issue Date: 10/6/2021

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Long Term Corrective/Preventive Action (Include actual or anticipated completion date.):

Corrective/Preventive Action	Assigned to:	Target Completion Date	Actual Completion Date:
Currently assigning owner to Mike Yoder – Leader of Safety to review procedure to meet the GMP 22716 standards.	Mike Yoder	11/6/2021	10/18/2021

Document(s) to be generated, revised, or withdrawn:
Updated procedure GEN 3.5-001 Personnel Hygiene & Health

Person responsible for Verifying Corrective/Preventive Action: Greg Goodman Date: 10/18/2021

FOLLOW-UP (To be completed by Quality System Coordinator or designee only)

Verify the corrective actions have been taken:			The effectiveness of this corrective or preventive action is required to be evaluated within ____ days following completion to determine effectiveness. (Provide description of method used to verify effectiveness.)															
Corrective/Preventive actions:	Verified complete (date/initial):																	
Procedure updated	GVG	10/18/2021	<table border="1"> <thead> <tr> <th>Description of Effectiveness Review</th> <th colspan="2">Verified Effective (date/initial):</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Description of Effectiveness Review	Verified Effective (date/initial):													
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Responsible Person submitted acceptable evidence (attach evidence if possible) Follow-up Audit Required
 MGT Team decides other action

Auditor / Quality System Coordinator: _____ Date: _____

Corrective/Preventive Action Accepted? Yes No
If not accepted, new CPAR number assigned: _____ Date Issued: _____

CPAR Closed
ISO 22716 Management Rep.: Greg Goodman Date: 10/18/2021

Filed: Original in Quality Files, Copy posted to Quality Intranet Site

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3.5 Personnel hygiene and health

3.5.1 Personnel hygiene

3.5.1.1 Hygiene programmes should be established and adapted to the needs of the plant. These requirements should be understood and followed by every person whose activities take them into production, control and storage areas.

3.5.1.2 Personnel should be instructed to use hand washing facilities.

3.5.1.3 Every person entering production, control and storage areas should wear appropriate clothing and protective garments to avoid contamination of cosmetic products.

3.5.1.4 Eating, drinking, chewing, smoking or the storage of food, drink or smoking materials or personal medication in the production, control and storage areas should be avoided.

3.5.1.5 Any unhygienic practice within the production, control and storage areas or in any other area where the product might be adversely affected should be forbidden.

3.5.2 Personnel health

Steps should be taken to ensure, as far as is practicable, that any person affected by an apparent illness or having open lesions on the exposed body surface should be excluded from direct contact with product until the condition is corrected or determined by medical personnel that the quality of cosmetic products will not be compromised.

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		Implementation-Date¶	10/18/2021¶	
		Last-Reviewed/Update-Date¶	10/18/2021¶	
Document-Owner:¶	Mike-Yoder¶	Approval:	Richard-Vergara¶	Revision-#:¶ 1¶

1. → **Purpose:¶**
 - 1.1. → To establish guidelines for Personnel Hygiene and Health for the Tissue Manufacturing Operations.¶
2. → **Scope:¶**
 - 2.1. → This procedure applies to all aspects of Tissue Operation at the Calhoun Plant.¶
3. → **Guidance Documents:¶**
 - 3.1. → Resolute Forest Products Current Good Manufacturing Practices, September 2016¶
 - 3.2. → ISO-22716 Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices, November 15, 2007.¶
4. → **Definition¶**
 - 4.1. → N/A.¶
5. → **Procedure:¶**
 - 5.1. → To protect product against contamination Tissue will follow the below guidelines:¶
 - 5.1.1. → Clothing shall be reasonably clean and in good repair while working in the Tissues areas, following company dress code policy.¶
 - 5.1.2. → Personal hygiene of each employee shall be maintained at all times while on duty.¶
 - 5.1.3. → Hands shall be cleaned before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated.¶
 - 5.1.4. → Cut level 4 Gloves shall be worn at all times unless handling finish product.¶
 - 5.1.5. → Jewelry shall not be worn in Tissue production areas to prevent possible contamination.¶ Exceptions to this rule are as follows:¶
 - → Watches carried at or below the waistline, or have break away bands which are acceptable.¶
 - 5.1.6. → Gloves shall be worn to cover any bandages. LATEX is NOT permitted in Tissue Converting or Tissue Production areas.¶
 - 5.1.7. → Long hair or braids more than 1" must be secured. Barrettes should not be used – rubber bands or similar are acceptable to secured hair. Accessories should not include beads.¶
 - 5.1.8. → Clothing or any other personal belongings shall be stored in designated areas, away from converting operations or Paper production areas.¶

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- 5.1.9. → Food or drink cannot be consumed on the operating floor. Only clear water is allowed on operating floors in both Converting and Tissue Machine areas.¶
- 5.1.10. → Any food/drink transported through the Tissue or Converting facilities must be covered. Glass containers are prohibited.¶
- 5.1.11. → Smoking is NOT permitted inside of the Resolute FP Mill.¶
- 5.1.12. → Fingernail polish and false fingernails shall not be worn. Fingernails shall be short and clean. False eyelashes shall not be worn in Tissue converting areas.¶
- 5.1.13. → Snap off type razor blades are not allowed.¶
- 5.1.14. → Any chemicals used in Tissue Converting areas must be pre-approved by Resolute.¶
- 5.1.15. → Resolute Tissue Converting operations containers will be labelled and used only for materials following the labelled instruction.¶
- 5.1.16. → All equipment or tools are cleanable (wooden handles are not preferred).¶
- 5.1.17. → All contractors must comply with GMP procedures.¶

6. → **Attachments:¶**
 - 6.1. → N/A.¶

Revision Record¶

DATE:¶	Revision-Number:¶	REASON-FOR-CHANGE:¶
10/25/16¶	2¶	Initial Release¶
10/18/2021¶	1¶	Change-Owner/Approval, updated 5.1.4,5.1.5,5.1.6, 5.1.7.¶