R20.35:PRI Assessment Documentation - Corrective Action Notification –

PRI Certification
PERFORMANCE REVIEW INSTITUTE

PLEASE PRINT

Company Name			
Plant/facility		Auditee No.:	
Standard(s)		Audit Type:	
Date(s) of	Start:	Finish:	
Lead/Team Auditor(s)			
Coordinator		Mandays:	

1. Contact Name: _____

2. Nonconformity / Discrepancy Number: _____ ☐ Hold (major) ☐ Minor ☐ Potential Product Impact?

3. Classification Justification (H/M):

4. Standard (as applicable) / Requirement (# and description):

Nonconformity Description (Basis of Root Cause Analysis and Corrective Action):

Objective Evidence Observed (Basis of Correction):

5. PRI Lead Auditor Signature/Date: _____

6. Acknowledgement Signature/Date: _____

7. Client Internal Corrective Action#: _____ If Sampling Scheme ☐Site specific ☐Systemic

Add reference to PRI CAN# (see line item #2 above) on your internal corrective action form. *Refer to page two for additional instructions.*

FOR PRI USE ONLY: Correction and Corrective Action Plans reviewed: Plans accepted ☐ Provide additional information ☐

Name/Date: _____

PRI verification of implementation and effectiveness, Name/Date: _____

Nature of Verification:

Client Instruction on Required Content - Your internal corrective action form must address the following four items (on SRI's website, refer to QP 6.0, Post-Audit Registration Procedures, section 2.2 for additional guidance):

A. **CORRECTION:** Your investigation should start with the information provided on page 1 of this form, in section 4, **Objective Evidence Observed.** Because PRI's audit is based on a sample, your investigation must identify and document the full extent of the nonconformity. If product included within the scope is impacted, Correction plans must include product containment. Include target dates/responsibility for completion of all plans. Where possible, use clear, data based statements to describe your investigation. Plans for Correction must be appropriate to the scope of the nonconformity and its effects.
   - For example, if PRI identified a problem with incomplete inspection records (2 instances observed/ documented on page one), your investigation statement may either read:
     < Reviewed 30 inspection records, with samples taken from all shifts. No additional nonconformity was observed.
     < (Or) Reviewed 30 similar records, with samples taken from all shifts. Ten (10) additional nonconformities were observed, all from the 3rd shift.

B. **ROOT CAUSE ANALYSIS**: Your root cause analysis should start with the information provided on page 1 of this form, in section 4, **Nonconformity Description**. The methodology used in determining why the Management System was not followed and/or effective techniques (such as, 5 Why, fishbone, cause and effect, FMEA, etc.) must be described. Also, record a description of the identified Root Cause(s).
   - For example: 5 Why analysis concluded that communication plans, regarding the importance of completing inspection records and the potential consequences of incomplete records are inadequate.

C. **CORRECTIVE ACTION:** Your plan to implement Corrective Action must describe the actions needed to remove the root cause(s) from the management system. Include target dates/responsibility for each aspect of the plan. Requirements for corrective action plans vary according to the reference standard and or customer requirements. Refer to applicable requirements to ensure your plans address all specified requirements.
   - For example: Operations Manager will update the communication plan by XYZ date to include written postings and face-to-face communication from supervisory management during quarterly lunch box employee meetings. These communications will stress the importance of completing inspection records and the consequences of incomplete records. This will be a regular topic until monitoring confirms employees consistently complete required records.

D. **VERIFICATION:** Your plan for verification must include both Correction and Correction Action. In addition, conclusions regarding effectiveness must be documented. Include target dates/responsibility for each aspect of the verification plan. This step can occur only after sufficient data or information has been collected and analyzed. PRI's Lead Auditor cannot begin the closure review until your verification plans are complete and documented.
   - For example: Internal auditors reviewed 10 records per shift across a 6-week period. No incomplete records were observed, so the action plans are effective.

Client Instructions on Required Timing - The auditee must return this form as specified (days = calendar days) with internal CA form attached, to the PRI auditor via e-mail [(first initial+last name)@sriregistrar.com or first initial+last name]@p-r-i.org] and a copy to PRI Audit Operations Coordinator, see audit plan cover page for email address to your audit operations coordinator [first initial+last name]@sriregistrar.com or first initial+last name]@p-r-i.org] (e.g., smazur@sriregistrar.com or smazur@p-r-i.org). For most standards, responses **must be returned to PRI within 30 days** with correction and corrective action plans, including responsibility and timing. Some standards require shorter response times and those timing requirements will be communicated by your Lead Auditor.

a) For all standards except as noted below, once the plan is accepted, closure of minor CANs will be verified at the next scheduled event.
b) For AS9100/AS9120, refer to Form 4, AS9104/1 section 8.4 nonconformity management, ICOP resolutions and FAQ 4.
c) Hold (major) CANs – In most cases, verifications are carried out on-site. For most standards, correction, determination of root cause(s), and corrective action plans are required **within 30 days** of the event, closure within 90 days of issuance. For AS9100 or 9120, see b). above.
d) For sampling clients – Refer to R20.114 for proper handling of corrective actions.

Notice - Failure to provide timely and complete action plans and/or ineffective action plans may results in changes to the status of your certificate or its withdrawal.