Dear PRI Registrar Auditors,

This advisory has been compiled in response to a nonconformance discovered by ANAB during our office audit last year. Two of our auditors accepted less than acceptable root cause for their findings.

The finding detailed the following:

A review of the root cause and corrective actions for Company A showed that the root cause and corrective actions were not fully acceptable and (in one case) - reflect a restatement of the problem without sufficiently addressing the root cause.

In the other case the response to the nonconformance that was accepted by PRI - the corrective action does not address the root cause of the nonconformance (identified by the client as "lack of responsibility of management").

In the future, PRI Registrar expected that their auditors and clients will be adhering to the following process for effective Nonconformance Management. If there is evidence that nonconformances are not being handled in accordance with this process, the nonconformances will be returned to the auditors and or clients for correction or clarification.

To aid in the dissemination of this methodology, this process will also be shared with our clients. Auditors should feel free to also share this advisory with clients as the need arises.
PRI Registrar Process for NCR Review

Overall
NCR responses should be reviewed in three parts: containment, root cause analysis, and corrective action. In reviewing the three parts, PRI Registrar will look for a plan and evidence that the plan is being implemented. In some cases, the client may take action but not provide a plan; this is acceptable as long as the following guidance is met. In all cases, however, the original NCR statement and requirement(s) referred to must be addressed throughout the responses.

Containment
To be fully accepted, if containment is appropriate, the response must include the following:

A. The extent of the nonconformity has been determined and contained.
   a. The nonconformity has been corrected and the response is written in the past tense (e.g., “The lot was re-inspected using the proper tooling” rather than “The lot will be re-inspected using the proper tooling”).
   b. The Client has examined the system to determine if there are other similar issues that need to be also corrected (how wide spread) and has also addressed the extent of the spread in its response.
   c. Include the evidence that PRI Registrar found and any other evidence that the Client may have found.

B. If containment cannot be immediate, a plan to correct the NCR may be appropriate and shall include:
   a. A schedule (dates) for implementation
   b. Identification of the parties responsible for the actions.

C. If applicable, indication that all parties involved have been informed of the problem identifying all groups (auditors, customers, internally affected parties, etc.)

D. Evidence that the containment was implemented or the containment plan is being implemented.

Root Cause Analysis
To be fully accepted, the root cause response must follow this guidance:

A. The root cause should not simply restate the finding or the direct cause.

B. The root cause should not be a brief expression of fact that neither explains away the situation nor rationalizes the condition.

C. The root cause should include analysis beyond the direct cause to the determination of the true root cause (e.g., an individual not following a process would be a direct cause, and determining why the individual did not follow a process would lead to the true root cause).

D. The root cause statement must focus on a single issue.
   a. If more than one cause is identified (e.g., training and inadequate work instructions), then two corrective action plans must be submitted.

E. The root cause statement must address a fundamental issue without any obvious “why” questions remaining.
a. If a “why” question can reasonably be asked about the root cause analysis, this indicates that the analysis did not go far enough.

**Corrective Action**

To be fully accepted, the response must include the following:

A. The corrective action or corrective action plan shall address the root cause(s) determined.

B. To be acceptable, the plan shall include:
   a. Actions to address the root cause(s),
   b. Identification of the parties responsible for the actions, and
   c. A date schedule for implementation.

C. To be acceptable, the evidence of implementation shall include enough evidence to show that the plan is being implemented as outlined in the response and on schedule.