Dear Auditors,

In the cases of ISO 9001 and ISO 14001 initial and recertification audits, as well as surveillance audits in all programs, PRI Registrar has long maintained a practice of “downgrading” an identified major nonconformance after reviewing an acceptable response from the client. Considering some of the clarifications presented in the new ISO 17021:2015 standard, PRI Registrar is changing the expectations surrounding major nonconformities, as detailed below.

The presence of a major nonconformity indicates a significant, systemic problem, or some other serious breakdown in the client’s management system. Major nonconformities should never be taken lightly. A new version of ISO 17021, the standard which governs a certification body’s activities, has been issued; and it provides a bit more clarity with regard to the expectations when major nonconformities are identified.

For initial and recertification audits, ISO 17021:2015, section 9.5.2 (b), states the following:

9.5.2 Actions prior to making a decision

The certification body shall have a process to conduct an effective review prior to making a decision for granting certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification, including, that:

(b) for any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions.

This indicates that major nonconformities must be fully closed prior to making a decision to issue a certificate.
For surveillance audits, ISO 17021:2015, section 9.6.1 (a) states that a certification body may maintain a client’s certification based on a positive conclusion by the audit team leader without further independent review and decision, provided that: (a) for any major nonconformity or other situation that may lead to suspension or withdrawal of certification, the certification body has a system that requires the audit team leader to report to the certification body the need to initiate a review by competent personnel, different from those who carried out the audit, to determine whether certification can be maintained.

The “system” that PRI Registrar will utilize will simply be the audit report. If you discover a major nonconformity during an audit, it will be documented as such in the NCR table of the audit report. Likewise, if you run into a situation which may necessitate the suspension or withdrawal of a certificate, we expect you to indicate as such in the “Auditor Recommendation” section of the audit report. During the review of the audit documentation, client managers will watch for these situations and alert the quality staff appropriately for an independent review of the situation.

Considering these clarifications, PRI Registrar is implementing the following changes / expectations with regard to major nonconformities with audits beginning **February 15, 2016:**

1) For initial and recertification audits, any identified major nonconformities must be verifiably closed before a certificate can be issued. You are no longer permitted to downgrade a major nonconformity and simply accept the response. **Closure of the nonconformity may require a follow-up special surveillance audit, depending on the nature of the issue.**

   **NOTE:** For aerospace audits, the industry still expects that all NCRs, regardless of major or minor criticality, be verifiably closed prior to certificate issuance. This is above and beyond the baseline expectations of ISO 17021:2015.

2) For surveillance audits, any identified major nonconformities will trigger an independent review by quality staff. Quality staff will review the major nonconformity and determine whether certification can be maintained, working in conjunction with the audit team leader. Again, depending on the nature of the nonconformity, and the recommendation of the quality staff review, a follow-up special surveillance may be requested / required to address the issue to ensure certification can be maintained.

Please let us know of any questions or concerns related to this change in our process.

We appreciate your adherence to this advisory.