SUBJECT: Compliance with Legislation and Regulatory Requirements

APPLIES TO: ANAB-Accredited and Applicant Certification Bodies

PREFACE

This Accreditation Rule is intended to prevent a certification body (CB) from accepting an affirmative statement in lieu of obtaining audit evidence that an organization has a satisfactory management system for ensuring compliance.

To clarify, a CB certifies conformance to a management system standard that may include requirements for compliance with legislation and regulatory requirements, but the CB is not conducting a compliance audit and, therefore, cannot certify legal compliance. This applies for all management system standards, including but not limited to ISO 9001, ISO 14001, ISO 22000, ISO/IEC 27001, ISO/IEC 20000-1, ISO 28000, ISO 13485, ISO 37001, ISO 45001, ANSI/ASSE Z10, CSA Z1000, BS OHSAS 18001, RIOS, Responsible Recycling (R2), and e-Stewards®, and AQMS (AS9100, AS9110, and AS9120).

EA-7/04 (which can be downloaded free of charge from www.european-accreditation.org) is a good reference providing additional information about the difference between certification for conformance and compliance. Although EA-7/04 is specific to an ISO 14001 environmental management system, the concepts apply to any management system that includes requirements for compliance with legislation and regulatory requirements.

ACCREDITATION RULE

1. A certification audit is an audit of a management system to determine conformance to the standard. While compliance is a part of the management system, the certification audit is not an audit of full compliance with all applicable regulatory requirements. Therefore, a CB shall not certify legal compliance and shall not otherwise provide statements or declarations of legal compliance as a result of a certification audit.

2. A CB may certify an organization or permit its certification to continue despite observed legal non-compliances, provided the CB is satisfied that the management system addresses such non-compliances and when in the aggregate such non-compliances are not determined to indicate a major nonconformity.

3. During the initial and continuing certification processes, it is relevant and necessary to gather sufficient data on the organization’s compliance with relevant legislation and regulations to determine whether the organization’s systems conform to the standard.

4. In the event that certain specific data or other information related to legal or regulatory compliance are not made available to the CB for review because of an assertion of legal privilege or their proprietary nature, certification shall not be granted or shall not continue, unless the CB can demonstrate through objective evidence that the full system requirements relating to legal compliance, covering the applicable section of the standard, have been effectively implemented by sufficiently documented and verifiable means. This would include at a minimum a procedure for evaluating legal compliance, objective evidence of its implementation, objective evidence of compliance review by management, and objective evidence of implementation of identified corrective actions. In such cases, the CB’s relevant requirements shall be stipulated in the certification contract agreed with the organization, and the evaluation methodology to be employed by the CB shall be documented in its audit plan.