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Use of Third-Party Accreditation to Assess Regulatory Compliance

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That is: Don't shoot the messenger.

The Third-Party Accreditation Reality

- Federal and state agencies are now or will be using third-party programs to assess regulatory compliance.
 - e.g., DoD ELAP, EPA (NLLAP and Energy Star), FDA, NJ, FL, MN
- These regulatory agencies are managing change, taking on new roles and overseeing these third-parties.
- Some agencies are being directed to do this, others have developed programs under existing statutory authority.
- Some state agencies have statutory restrictions on recognizing or using third-party programs.
- Some compliance assessment activities may be inherently governmental, and thus require performance by government personnel. The EPA has previously stated "EPA does not believe that laboratory accreditation is an inherently governmental function." Paul Gilman, 2002
- A third-party program is just one of many regulatory approaches agencies may adopt.

Broad reasons support the growing use of third-party programs:

- Many agencies are faced with assuring compliance of accredited laboratories with declining resources.
- Shrinking government budgets.
- Can shift some of the financial obligation on governments performing assessments and managing accreditation programs onto the third-party accrediting bodies and accredited laboratories.
- Reduction in the need for government to employ their own laboratory assessment personnel.
- More accreditation stakeholders view third-party programs as the best laboratory accreditation model.
- Third-party programs may leverage private resources and expertise in ways that make regulations more effective and less costly*.
- Third-party programs may enable more frequent assessments (e.g., surveillance)

- Regulatory third-party programs raise a host of important issues.
 - Form "public-private governance" in which private sector plays roles that have been traditionally viewed as governmental.
 - If not well-conceived and well-operated they may undermine the achievement of regulatory goals and impose unnecessary costs on agencies and regulated entities.

- Agencies that establish third-party programs generally cannot or do not delegate their regulatory authority. They authorize third-party programs to assess conformity.
- Regulatory agencies rely on these conformity assessments in their own enforcement of regulatory requirements.
- The goal is to leverage expertise and resources in the private sector to serve regulatory objectives.
- Regulatory agencies must remain ultimately responsible for achieving regulatory objectives.

- Recommendations for an agency when deciding to develop a third-party program:
 - Consider relevant resources available (nongovernmental and governmental).
 - Compare regulatory approaches evaluate the advantages and disadvantages:
 - Would a third-party assessment be effective?
 - Costs and resources needed to run a program.
 - Agency capacity to perform effective oversight.
 - Potential for agency to achieve efficiencies through reducing its direct assessment costs and resource needs.
 - Costs to regulated entities for assessment activities.
 - Benefits to and incentives for regulated entities to contract with third-party.

- Considerations for an Agency when establishing a Third-Party Program:
 - Establish rules to help ensure high degree of rigor and independence.
 - Use existing standards (e.g., TNI, ISO 17011, ISO 17025).
 - Ensure effective oversight to ensure third-party is fulfilling its regulatory purpose.
 - Set forth how it intends to conduct oversight and deal with any poor performance of third-parties.
 - Ensure appropriate level of reporting to agency.
 - Promote transparency to the public (i.e., public access to information about program).

Need Agency Metrics of Success for Evaluating Third-Party Programs

- Reliability and Accuracy of Third-Party
 Determinations Competence, Independence
 and Consistency.
- Rates of Compliance (is it improving)
- Agency Capacity to Administer Third-Party Program
- Public Acceptance
- Industry Acceptance Incentives to Participate

Example: DEPARTMENT OF DEFENSE

- DoD Environmental Laboratory Accreditation Program (DoD ELAP) laboratory accreditation of environmental testing laboratories performing testing in support of restoration programs at DoD operations:
- 4 U.S. Accreditation Bodies (AB) were recognized based on their agreement to abide by the conditions and criteria set for by DoD ELAP:
 - The U.S. AB must:
 - Maintain ILAC MRA signatory status and operate in accordance with ISO/IEC 17011.
 - AB must assess to the requirements for ISO/IEC 17025-2005, 2009 TNI Standard, and the DoD Quality Systems Manual (QSM).

DEPARTMENT OF DEFENSE

- Environmental Laboratory Accreditation Program (cont)
 - The U. S. AB must:
 - Provide the EDQW with assessment reports and accreditation information.
 - Inform EDQW of upcoming assessments and submit to observation by EDQW personnel.
 - Participate in meetings with the EDQW as part of continual improvement efforts.
 - Allow EDQW to attend its ILAC MRA peer evaluation.
 - Maintain DYNEX spreadsheet of accredited laboratories on EDQW website.

Stakeholders Perceived Benefits of Using Third-Party Programs

- Enhanced consistency between assessments.
- Pool of experienced and knowledgeable assessors.
- Ability of ABs to promptly deal with poor performing assessors and rectify the situation (e.g., don't use again).
- Confidence in ABs based on the requirement for peer evaluations.
- Agencies maintain oversight of their individual programs.
- Agencies retain primacy in the issuance of licenses, certificates, etc..
- Agencies still collect fees to support their oversight role and costs.
- Agencies gain increase in resources that were dedicated to performing assessments and managing various aspects of accreditations.
- Increased flexibility to handle new accreditation demands.

Why Public/Private Partnerships can be Successful

- Programs can be tailored to specific regulator needs but are based on common standards: TNI, ISO/IEC 17011 and ISO/IEC 17025.
- Partnerships enable varying degrees of oversight by agencies based on the risk level.
- These partnerships place the costs of accreditation on the laboratories being assessed/audited.
- They fit seamlessly into the accreditation bodies' programs and systems while easily being catered to the specifier (e.g., DoD, FL).

Third-Party Programs:

"A Regulatory Agency*

approves

Accreditation Bodies

that accredit

Conformity Assessment Bodies

that assess whether

Regulated Entities or Regulated Products

are in conformity with

A Regulatory Standard"

Administrative Conference of the United States-Recommendations (12/6/12)

Some ongoing issues/topics to consider while moving forward:

- Enforcement power must stay with regulatory agency.
- Retain agency oversight role.
- Agency makes final decision on accreditation, issuance of state license or certificate.
- Resistance of some NELAP states to the idea in general.
- May require revisions to current regulations (federal and state).
- Must have public access requirements (e.g., FOA).
- Should not reduce amount of transparency.
- Protect against conflict of interest.
- Ensure able to assess and quickly correct any problems in performance (Accrediting Bodies and Assessors).
- Legal issue of "delegation of regulatory authority" may rise.
- Discussions on use of third-party programs may involve political, policy and labor-union considerations.

Audience Participation Time

Great opportunity to have a brief open discussion and hear from others in audience.

Thank you!

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