3933 US Route 11
Cortland, NY 13045

Telephone: +1 (607) 753 6711
Facsimile: +1 (607) 753 1367
www.intertek.com

28 May 2010

Kathleen Vokes
United States Environmental Protection Agency
1310 L St., NW
Washington, DC 20005-4113

Re: Draft Laboratory Requirements

Dear Ms Vokes:

Intertek appreciates the opportunity to participate in the stakeholder process and offer comments on the Draft Conditions and Criteria for Recognition of Laboratories for the ENERGY STAR® Program.

We have reviewed your draft document and offer the attached comments for the recognition of laboratories under the program.

Thank you for the opportunity to offer comments on this document. We look forward to working with the EPA and DOE to support improvements to the ENERGY STAR Program.

Best Regards,

Craig Davenport
Quality & Accreditation Manager
Intertek

Conditions and Criteria for Recognition of Laboratories for the ENERGY STAR® Program
DRAFT

In order to serve as an accredited laboratory for the ENERGY STAR program, a laboratory shall agree in writing to comply at all times with the following requirements:

General Requirements:

- Maintain accreditation to ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories," by an EPA-recognized Accreditation Body (AB). Noteworthy elements of ISO/IEC 17025 include requirements that laboratories shall:

    - have a policy that sets out quality objectives, commitments and operational procedures;
    - employ experienced personnel who have the education and training needed to conduct the tests;
    - have the physical plant facilities and test equipment needed for proper testing;
    - ~~develop and maintain separate laboratory test methods for each accredited ENERGY STAR test method that detail how testing will be conducted utilizing the laboratory's test facilities, fixtures, equipment and personnel;~~

Comment: This section details specific requirements of ISO 17025, however 17025 does not specifically require separate laboratory test methods for each standard in an accreditation scope. In fact, many ABs accept that the test standard itself is appropriate as a laboratory test method. To ensure the expectations of EPA are met, we propose that this bullet point be removed from this section and separated as a specific EPA requirement independent of ISO 17025.

    - ensure that measuring equipment is accurate and calibrated and that calibration records are maintained;
    - maintain a record of all original observations, test data and calculations; and,
    - maintain arrangements to ensure the freedom of laboratory management and personnel from any undue internal or external commercial, financial or other pressures and influences that may adversely affect the quality of their work.

- Develop and maintain separate laboratory test methods for each accredited ENERGY STAR test method that detail how testing will be conducted utilizing the laboratory's test facilities, fixtures, equipment and personnel;
- Notify EPA/DOE immediately of any attempt to hide or exert undue influence over test results.
- Have recorded in its Scope of Accreditation its specific competence to carry out the test methods as outlined in the ENERGY STAR Program for which the laboratory intends to test products.[1]

Note: EPA plans to add a section to each ENERGY STAR specification where the specific test methods that must appear on the recognized laboratory's Scope of Accreditation will be enumerated.

Comment: We support the addition of specific test methods that must appear on the Scope of Accreditation. The inclusion of this information in the ENERGY STAR specification will provide clarity and eliminate confusion between ABs

[1] The relevant test procedures are included in the product testing section of each ENERGY STAR specification.

NOTE: To decrease the burden to laboratories and accreditation bodies, EPA will not require laboratories to update their Scopes of Accreditation when an ENERGY STAR specification is revised. However, EPA will *require that the laboratory ensures its methods remain consistent with the test methods described in the program requirements of the currently effective version of the specification. Further, major changes in test method, for example, when a specification revision calls for a different test method altogether from the preceding specification version, will necessitate a Scope of Accreditation update to reflect the newly required test method.*

- Allow EPA or an EPA-appointed representative, at its discretion, to witness any testing performed for qualification or verification of qualification to the requirements of the ENERGY STAR program. EPA or its appointed representative agrees to operate solely as an observer and not interfere in any way with the testing activities of the laboratory.

Inter-laboratory Comparison Testing:

- Agree to participate in relevant and available inter-laboratory comparison testing (ILC) when EPA/DOE deems it necessary.

- Carry out ILC in accordance with normal testing/calibration and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.

- Submit to EPA/DOE upon request:

    - The results of ILC;
    - The analysis of those results; and,
    - Detailed corrective action responses for any outlying or unacceptable results.

Reporting:

- Submit to EPA evidence of accreditation including:

    - accreditation effective date;
    - accreditation expiration date;
    - ENERGY STAR-relevant accredited test methods; and,
    - a list of qualified personnel per ENERGY STAR-relevant accredited test methods.

- Submit to EPA documentation demonstrating the impartiality and freedom of laboratory management and personnel from any undue internal or external commercial, financial or other pressures and influences that may adversely affect the quality of their work. In the case of "in-house" laboratories, this shall include evidence that:

    - laboratory employee compensation or annual bonuses are not tied to the financial performance of the parent company;

- laboratory engineering personnel do not originate with or return to the parent company, or otherwise look to the parent company for career advancement;
- laboratory employees are required to participate and regularly pass third-party ethics and compliance audits conducted in accordance with the International Federation of Inspection Agencies (IFIA) Compliance Code or equivalent standards for ethics and compliance programs; and,
- mechanisms for reporting and responding to attempts to exert undue influence on the test results are in place. This shall include establishment of an external system for employees to make such reports and follow-up on such claims, as well as regular education of staff as to what avenues are available to them should they identify attempts to influence test reports.

Note: EPA is proposing to supplement the ISO/IEC 17025 requirements associated with ensuring the independence of the in-house laboratory from the manufacturer. EPA's goal is to allow for in-house testing with sufficient controls to ensure such testing remains independent.

Comment: Throughout this document the EPA uses the term "in-house" laboratory. It would be beneficial to adopt internationally accepted terms such as "first-party and second-party" laboratories. This would clearly separate (independent) third-party laboratories from (non-independent) manufacturer's laboratories (first-party) and their agents or distributors (second-party). We believe this distinction is important in communicating the intent of this section of the requirements.

- Authorize the laboratory's AB to share with EPA:

  - the laboratory's assessment schedule;
  - copies of assessment documentation including corrective action plans, deficiency resolutions; and,
  - laboratory feedback on the assessors or assessment process.

Comment: In the AB document, this requirement is prefaced with the phrase "Upon request", we believe that language should also be incorporated here. As a standard practice, our accreditors do not take or maintain separate archives of Intertek files. The information reviewed in an audit often involves customer confidential information as well as Intertek proprietary business processes. In recognition of these concerns, our accreditors do not take copies of audited documents. It is important for EPA to have access to this information when required, however we do not believe that assessment documentation should be routinely shared between the AB & EPA. A best practice might be to include a provision allowing the EPA to come in and review the audit materials directly, in the event there is a need.

For the same reasons, it is also our concern that once the documentation is in the hands of the EPA it might be accessible under FOIA. We suggest that provisions are put in place to ensure that Exemption 4 under FOIA is applied to prevent disclosure of assessment documentation and Exemption 5 is applied to any internal deliberative/assessment reviews that EPA may conduct using this material. The accreditation audit process is premised upon maximizing the free flow of information and identifying, as directly as possible, any areas where Intertek can make improvements. Candor is essential. Should these protections not be in place, so that audit findings would be available to customers, competitors and the public at large, the conduct of an audit would change. It would become far more difficult to have open and constructive interactions with our accreditors. We assume that our competitors would share these same difficulties in managing disclosures to accreditors.

- Report to both EPA and the laboratory's AB within 30 days of any major changes that affect the laboratory's:

    - legal, commercial, organizational, or ownership status;
    - organization and management, e.g., key managerial staff;
    - policies or procedures, where appropriate;
    - location;
    - personnel, facilities, working environment or other resources, where significant; and,
    - other such matters that may affect the laboratory's capability, scope of recognized activities, or compliance with the ENERGY STAR requirements and relevant technical documents.

Comment: Although we understand the need for transparency to the EPA, these requirements are in place as a condition of accreditation and the AB should be allowed to manage this information from the Laboratory. Asking both Laboratory & AB to report is a duplication of effort and likely will cause confusion. We recommend that the Laboratory reports changes to the AB, and the AB advises the EPA of those changes should it be determined that it might affect the ENERGY STAR accreditation scope. Using this approach will clarify the responsibility for the flow of information and help to define what is a "major" change that requires EPA notification.

- Forward any questions related to ENERGY STAR test methods to EPA for resolution and abide by the decisions of EPA relative to the resolution of those disputes.