SCOPE EXTENSION BY DOCUMENT REVIEW

Instructions:

1. Complete and submit a scope of testing template for each appendix, regardless of whether a) a request is being made to add analytes to an existing accredited appendix or b) a request is being made to add a new appendix. If requesting addition of analytes to an existing accredited appendix, be very clear as to the appendix number.

2. Review P02-03 CALA Proficiency Testing Policy for Accreditation to ensure that proficiency testing (PT) requirements are met.

3. Submit test methods, method validation, and, where applicable, PT results. If providing the documents and records by e-mail, be very specific as to the file names or provide a link.

    Note: As per A06 – CALA Accreditation Program, Policies and Procedures, the scope extension by document review may be rejected and the laboratory may require an abbreviated assessment.

Important: Proficiency Testing (PT) Requirements:

As per P02-03 CALA Proficiency Testing Policy for Accreditation, the 50% rule only applies for accredited analytes. Laboratories must demonstrate proficiency for all new analytes. Practically this means:

a. For analytes that are option i (CALA or non-CALA PT) or option ii: any non-CALA PT results must be submitted as part of the package AND the results must be entered on to the online web data entry. It is the responsibility of the laboratory to enter the PT results on-line prior to attaining accreditation. Generally, once the application has been processed, the laboratory may enter any PT results in parallel with the process of method validation and SOP review.

b. For options iv, vi and vi: please submit evidence of proficiency as part of the method validation package.

c. For analytes that will fall under the 50% rule once accredited and PT is available from an approved supplier, satisfactory participation in this PT must be completed prior to accreditation. Note this on the scope of testing template and submit the PT results as part of the submission package for review.

d. A non-detect is not evidence of proficiency. It must be demonstrated that the analyte can be detected and measured.