

TECHNICAL OPERATING PROCEDURE

PROCEDURE TITLE: Validation of Analytical Procedures

APPLICABILITY: Aquatic Ecosystem Health Branch

PRINCIPLE: The purpose is to provide the proper guidance for validation of analytical procedures. Before an analytical procedure can be used as part of a Good Laboratory Practice study where data may be submitted to regulatory agencies, the Study Director must make sure the proper agency guidance and recommendations are being adhered to and followed.

PROCEDURE:

- A. For studies submitted to U.S. Food and Drug Administration (FDA), follow Guidance for Industry #64, "Validation of Analytical Procedures: Methodology." Current FDA guidance can be found at www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052379.pdf. Reference the method used in the data management system.
- B. For studies submitted to U.S. Environmental Protection Agency (EPA), follow EPA guidance on method validation for analytical procedures. Current EPA guidance can be found at <http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm>. Many test guidelines are available but be sure the appropriate guideline is selected for the specific application. Reference the method used in the data management system.
- C. For all other analytical procedures, the Study Director will determine the criteria for validating the analytical procedures.

REFERENCE: None

Author:

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Technical Reviewer:

Chemist

Quality Assurance Review:

Quality Assurance Officer

Bureau Approval:

Acting Branch Chief, Aquatic Ecosystem Health

Change History Table

Revision No.	Date	Person Responsible	Description of Changes
06	March 26, 2019	Kim Fredricks	Updated header and footer to reflect QMS guidance of April 20, 2018. Added "Original" watermark