

Virginia Division of Consolidated Laboratory Services

QUALITY MANUAL TEMPLATE INSTRUCTIONS

For Noncommercial Environmental Laboratories, 1 VAC 30-45

August 13, 2009

Credits: This template was built from other templates and quality assurance manuals developed during training for Virginia's Environmental Laboratory Certification Program. Principle credit goes to Marlene Moore, President of Advanced Systems, Inc. who has been engaged in training environmental laboratories in Virginia for a number of years. DCLS is also grateful to the State of New York's Environmental Laboratory Accreditation Program. This program provides a QA Manual template on its website.

The Virginia Division of Consolidated Laboratory Services (DCLS) has developed a quality assurance manual template as a guide that may be used by environmental laboratories that are covered by 1 VAC 30-45, *Certification for Noncommercial Environmental Laboratories*, effective January 1, 2009.

This Quality Manual template provides a basic summary of practices and requirements necessary to implement a quality system. The template is not a requirement of the program. The template is a tool developed by DCLS to assist the laboratory in developing a quality system. The template does not supplant the need for the laboratory manager and quality assurance officer to thoroughly read, understand, and implement the requirements of the regulation for noncommercial laboratories (1 VAC 30-45).

The template is provided to assist laboratories that have limited experience writing quality assurance manuals. The template should assist anyone using it to develop a quality assurance manual that is specific to his or her laboratory and that incorporates the requirements of 1 VAC 30-45.

The template is organized into twenty sections, including a glossary. The template also includes suggested attachments. The laboratory using the template may adopt the format or modify the format for the laboratory's purposes.

Each section has a title, a list of 1 VAC 30-45 requirements, instructions, and examples. The requirements section provides the reference to language in 1 VAC 30-45 which the laboratory should read and understand before the section is written. The instructions and *examples* provided in the template should be considered as tools to be used when writing the quality assurance manual for the laboratory.

The instructions are provided to direct the writer to think about what should be included in the section. The writer may decide to include material not discussed in the template's instructions or may organize the material in a different fashion. These instructions should not be included in the completed quality manual.

Examples provided in the template (in shaded areas) present the kind of documentation that is pertinent to that section. (Remove the shaded area once you have inserted your own text.) Note that examples may apply to wastewater treatment facility labs and not to the template user's situation. The laboratory would benefit by making the quality assurance manual documentation as specific as possible to the system or processes that are or will be in place prior to an on-site assessment.

In a number of instances the quality assurance manual should reference standard operating procedures (SOPs) rather than reproduce the SOP information in the quality assurance manual. Passages that require you to enter information are highlighted in yellow. (The yellow highlight should be removed in your laboratory's quality manual.)

When the quality manual is completed, the Table of Contents may be automatically updated if section titles have not been altered through the editing process. Automatic

updates are done by clicking the cursor into the Table of Contents, which causes the section to become gray. Next, select the F9 key and choose “Update page numbers only”. If section titles have been altered, the title text must be classified as a Heading 1 or Heading 2 in the document outline, and when F9 is selected, the user must choose “Update entire table”. This process may be problematic if the heading classifications are inconsistent. If so, the Table of Contents may need to be typed.

DCLS suggests that the writer of the quality assurance manual for the laboratory save the template using the “Save As” feature with a different filename. This template is MS Word 2003-2007 compatible.