

“QA/QC and NELAP Compliance in Laboratory Automation and Information Management”

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ABSTRACT

Quality Assurance and Quality Control have long been focal points of attention for environmental laboratories. This is easy to understand when the importance of the data produced in environmental laboratories is considered. This data is used in decisions that affect large numbers of people in many ways. Some of these ways include financially, health concerns, property use, regulatory and legal issues. To address some major concerns about multiple sets of regulatory requirements being applied to environmental laboratories the National Environmental Laboratory Accreditation Program (NELAP) was created. Chapter 5 of this program addresses the QA/QC requirements for laboratories wishing to be accredited under the program.

Laboratory Automation software can be a powerful tool in helping a laboratory achieve NELAP compliance. What are the factors prompting laboratory leaders to automate? A closer look at the world they have to operate in reveals some key factors. In order to comply with the many environmental regulations that affect the industry, laboratory leaders must have the time and resources to learn about regulatory changes, plan for them, and implement those changes. With these factors in mind, laboratories are faced with real organizational challenges.

In this paper we will discuss how a computer based Laboratory Information Management System (LIMS) can help laboratories achieve NELAP compliance. The NELAP requirements from Chapter 5 (revision 16) will be discussed along with how each can be met using a computer based LIMS.