



**Your Partner in Isolator Validation**

825 Lynnewood Drive  
Waukesha, Wisconsin 53188  
Tel: 262-548-9748  
Fax: 262-548-9758  
Cell: 262-853-9748  
Email: rick@ardienconsulting.com

**Date:** January 24, 2014

**Subject:** Re-qualification Service – More than You Think

The purpose of this letter is to detail reasons why many of my customers continue to use Ardien Consulting Services to perform the annual re-qualification of their isolator system, year after year. Of course the primary reason to requalify your isolator system is because of regulatory mandate; however, the re-qualification services provided by Ardien Consulting Services are much more than you may realize and I am asking for a moment of your time to outline this, below.

The goal of re-qualification is to determine whether or not the vaporized hydrogen peroxide system is still able to bio-decontaminate the exposed, internal surfaces of the isolator, and the exposed, external surfaces of items placed within the isolator. Re-qualification establishes documented evidence that the vaporized hydrogen peroxide system can, and does, still perform effectively based on the defined process methods and specifications.

Ardien Consulting Services is the superior choice for re-qualification for the following reasons:

- Ardien Consulting Services has over 20 years of established expertise in isolation technology and vaporized hydrogen peroxide systems.
- Ardien Consulting Services provides telephone and email assistance, *free of charge*, for one calendar year after having been contracted to perform your re-qualification services.
- Ardien Consulting Services is a fully independent company; thus potential questions related to conflicts of interest are not applicable. When a company delegates its own employees to validate equipment, or when a company hires the manufacturer of the isolator to validate the isolator, questions of conflict of interest can, and sometimes are, raised by regulatory agencies. Hiring a third party, such as Ardien Consulting Services, eliminates any question or concern.
- As part of the re-qualification package provided by Ardien Consulting Services, a thorough system evaluation is performed that ensures the equipment is operating as originally validated. Only experienced isolator specialists such as Ardien Consulting Services are able to make this evaluation accurately. If the equipment is not operating as expected, Ardien Consulting Services will work with you, and the isolator manufacturer, to ensure the issue is resolved correctly and efficiently.
- Regulatory requirements associated with isolation technology and vaporized hydrogen peroxide systems change from year to year. Ardien Consulting Services will ensure your re-qualification is up to current industry standards and regulatory expectations.
- Ardien Consulting Services will ensure your employees are current on the newest developments associated with isolation technology and vaporized hydrogen peroxide systems.

Should you have any questions or would like to discuss my services in more detail, please contact me and I will be glad to provide a price quotation.

Thank you for your time and consideration.

Kindest Regards,

Rick Nieskes - Owner and Principal Consultant