

From: Luftman, Henry [HenryLuftman@microcln.com]  
Sent: Thursday, February 28, 2008 3:06 PM  
To: Costello, Mindy  
Cc: 'bpeters@nuaire.com'; Paul Lorcheim (E-mail)  
Subject: RE: [chlorine\_dioxide] Revised protocol

Attachments: 02-28-08 Protocol.doc

Mindy,

First, I thank the members of the committee for their thoughtful review of the CD protocol. I am attaching a latest revision, changed only on the basis of Dr. First's comments. Instead of using his expression of "2-strip BI", I have put in "pair of BIs". In either event, the previous version was in error here.

A week of validation experiments was performed at the NuAire facility in January testing method #1 as described within the protocol. I can issue a more complete report now if requested. It is believed that I erred in the handling of the BIs following the decontamination cycles, particularly as a result of the neutralization step that I performed using sodium thiosulfate solutions. As a result, we believe that there multiple false positive results. The error was not noted until 3 days into the study, given the time required for incubating the indicators. At that time, BI procedures were modified, and subsequent decontamination trials yielded almost entirely negative BI results.

I summarize here the results, referring to the cabinets as N1, N2, N3 and N4. (Review section #4 of the protocol for criteria of success and failure.) The study for N1 failed because one of three trials failed at 2 locations (protocol #4d). The study for N2 initially failed for the same reason. However, there was sufficient time to repeat a trial after the BI issue was resolved, with new trial results yielding only negative results. By the protocol (#4f), N2 would now be considered to have passed. The study for N3 failed because one of three trials failed (#4d) and because a failure occurred at the same site in two trials (#4e). All of the trials for N4 were performed after the BI issue was resolved, and all trials for N4 passed. Given limitations of time and supplies during the week of study, we were not able to repeat trials for cabinets N1 and N3. We the committee's consent, our hope is to rerun those tests following the testing of method #2.

The tests for method #2 will be performed by ClorDiSys Solutions, Inc on Baker cabinets at the Micro-Clean facility. This study is scheduled to commence on March 10 and should be completed within 2 weeks of that date.

I plan to issue a more complete report to the committee upon completion of the method #2 tests, at which time I will propose how we plan to repeat a portion of the method #1 tests and seek the teams agreement that successful results from those further studies would constitute meeting the validation goals of the entire program. Until then, I would be more than happy to respond to any questions or comments from the team.

Henry

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