

**From:** Michael Thurston  
**Sent:** Friday, May 11, 2012 2:53 PM  
**To:** mgiamei@medicalsalesmgmt.com  
**Subject:** FW: NECC Q1-question

FYI

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**From:** Barry Cadden  
**Sent:** Friday, May 11, 2012 2:26 PM  
**To:** ngoc.nguyen@tenethealth.com  
**Cc:** Michael Thurston  
**Subject:** NECC Q1-question

“0.5% excursion rate”?

The 0.5% excursion rate means that (1) of (200) individual clean-room air tests over the course of approximately 3 months fell outside an “acceptable” CFU ( colony forming units) range. All air tests at NECC are taken under normal working conditions = stressed conditions. Many compounding facilities do not test air quality under working conditions, but take samples when no employees are working within the clean-room. This is obviously not acceptable. This particular “out-of spec” test was taken in the most stressed area of our clean-room, the area just beyond the door of the people-anteroom. Every employee must pass through this area whenever entering or exiting this particular clean-room. After investigation it was determined that this particular test was taken at a time when 80% of all clean-room employees were returning from lunch break. The large number of employees passing through this area while the air sample was being taken obviously caused this out of spec result. This was determined to be an “extremely” stressed condition that it far beyond normal working conditions anywhere in this clean-room at any time. These air tests are occurring outside of any class-10 or class-100 laminar flow hoods/glove boxes where all critical operations occur.

Feel free to contact me if you have any other questions.

Regards,

Barry Cadden, R.Ph.