



306 W. Murray, Liberty, MO 64068 Local: 816 - 792 - 8250 Web site: www.airsafeonline.com

November 13, 2009

Effectively January 1, 2010 Air Safe, LLC. will no longer service any Containment Technologies Group, Inc. isolator if being utilized in conjunction with <797> Pharmaceutical Compounding-Sterile Preparations. As many in the industry are aware there has been an ongoing concern about the acceptability of these devices used in typical hospital pharmacy settings.

(http://www.mic4summaryjudgmenttruth.com/mic4_court_case/mic4_court_summary_truth.pdf)

(<http://www.insd.uscourts.gov/Opinions/AQ997002.pdf>)

Air Safe, LLC field data supports the decision to cease the servicing of these units. We have addressed our concerns with our clients which utilize this style of isolator for <797> compounding previously and feel that we can not jeopardize our professional integrity by “certifying” these devices to what the manufacture states. In our opinion these units are not inline with industry standards by definition denoted below. There have been multiple changes to the field testing methodology by Containment Technologies Group (CTG). We have addressed our concerns with CTG in the past and have not received satisfactory results. It should also be noted that Air Safe, LLC has sent two technicians to CTG to attend their formal training seminar which was held in March 2007.

Recently Air Safe received a letter from CTG which was addressed to a pharmacy client. This letter stated that:

As Mr. Alleman continued his interpretations he stated that in his **opinion** the MIC does not have unidirectional airflow. USP <797> states clearly *‘It is incumbent on the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet the standard’*. You have received from CTG a complete documentation package, this documentation package includes statements and videos of smoke tests proving that the MIC Family of Isolators have unidirectional airflow. Again, there is nothing left for ‘interpretation’ or ‘personal opinion’. The standard is very clear in it’s intent, expectations on personnel, as well as expectations on the manufacturer. Your MIC Isolator is compliant with the USP<797> standard.

Air Safe, LLC has not seen a visual smoke study from CTG that demonstrates uniform downflow over the entire work area.

The comment concerning “field testing” would lead one to believe that the test was conducted based on a standard and that the test was conducted in accordance with the standard. The reference given is the CETA guide, which is simply an example of testing and not a standard for USP<797>. Mr. Alleman is well aware from other attempts at influencing pharmacy personnel that the CETA guide is not the official USP testing standard and in fact he has been supplied with a letter from USP legal council that the CETA document is not to be considered a testing standard.

We at CTG believe that Mr. Alleman must have a reason for writing such an extensive letter. In the past he has expressed concerns about CTG, Inc. taking certification business away from his company. We are a one-stop shop for all of your USP<797> needs and have well over 1000 very satisfied clients throughout the world. Is his reason to protect his local Kansas City service business, to promote a competitor’s isolator, or to promote CETA? Unfortunately, we simply don’t know. We would be happy to provide you with contacts where he has attempted similar actions. We are very committed to our customers and feel badly that you have been subjected to any concern Mr. Alleman’s letter may have raised. We apologize for the inconvenience as well as the lack of professionalism that you are experiencing. We stand behind our products and service and sincerely hope to exceed your expectations at all times.

Air Safe stands behind its “opinion” that the CTG isolator discussed within this communication does not utilize unidirectional airflow across the entire work area and it should actual be considered a “turbulent flow” isolator. It is unreasonable to think that a manufacturer of a device is able to state that its unit operates as a uniform downflow device when the industry definition of this device (based on airflow characteristics) would dictate it as being a turbulent flow device. Video comparison of uniform downflow & turbulent downflow can be seen at:

<http://www.germfree.com/gallery/videos/split-screen-smoke-test.flv.php>

Uniform down flow definitions:

The ISO 14644-3:2005(E) states:

“3.4.7

unidirectional airflow

controlled airflow through the entire cross-section of a clean zone with a steady velocity and approximately parallel streamlines

Note: This type of airflow results in a directed transport of particles from the clean zone.”

The IEST-RD-CC011.2 states:

“unidirectional airflow

Air that flows in a single pass in a single direction through a cleanroom or clean zone with generally parallel streamlines. Formerly referred to as *laminar airflow*.”

...

“nonunidirectional airflow

Airflow that does not qualify as unidirectional because it has multiplicity of flow directions or multiple-pass circulation (eddies), or both.

Nonunidirectional airflow cleanroom (or clean zone)

A cleanroom or clean zone that is characterized by random, turbulent airflow vectors throughout the work zones.”

The air which comes in contact with the critical area (Direct Compounding Area (DCA) is not 100% first air, but a combination of first air and recirculated air within the chamber due to the entrainment of air into the supply air stream.

Secondly, Air Safe has only serviced 19 CTG isolators over the past years, so to assume Air Safe is only motivated by revenue or by protecting our “service business” or to “promote CETA” (<http://www.cetainternational.org>) is absurd. We are dedicated to providing professional comprehensive services to our clients which they have come to expect.

Air Safe’s relationships with its clients are built on trust, technical expertise and a common goal of ultimate patient safety. Air Safe will not jeopardize this relationship with its clients regardless of the outcome.

CTG mentioned in its letter to Air Safe that they are a “one-stop shop for all of your USP <797> needs”. There appears to be a conflict of interest in a manufacturer certifying their own devices, however, it is evident that CTG does not agree with this opinion.

Lastly, in my 20 years of experience in the HEPA filtered device certification industry I have never been compelled to cease the servicing of any other manufactured HEPA filtered device. I have personally worked with multiple manufacturers to assist in correcting deficiencies with positive results. This has not been the case with CTG.

If you have any comments concerning this letter please do not hesitate to contact me directly at mike@airsafeonline.com or 888-924-7723.

If you own a CTG isolator and need service or “certification” please contact:

Containment Technologies Group, Inc.
5460 Victory Drive, Suite 300
Indianapolis, IN 46203
Office: 317-713-8200 | Fax: 317-713-8201
<http://www.mic4.com/about/contact.php>

Sincerely,

Michael Alleman
President
Air Safe, LLC.