



To Whom It May Concern:

05/20/2008

Please accept this letter as a written guarantee of the following,

The MIC Isolator is absolutely, positively, 100% compliant with the newest USP<797> standard that takes effect on June 1st 2008!

According to the standard the Primary Engineering Control (LAFWs, BSCs, CAIs, CACIs) shall be unidirectional. The MIC Isolator is classified as a CAI while operating under positive pressure and as a CACI while operating under negative pressure. The MIC Isolator maintains unidirectional airflow within the direct compounding area and therefore meets this requirement.

Furthermore, the standard states that the CAIs and CACIs shall be placed in an ISO Class 7 buffer area unless they meet all of the following conditions:

1. The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of the CSP
2. Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations
3. Not more 3520 particles (.5 um and larger) per m³ shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer

The MIC Isolator meets and/or exceeds all of these conditions and therefore is not required to be placed in an ISO Class 7 buffer area (clean room) while operating as a CAI.

Additionally, the standard requires that CACIs be placed in a negative pressure clean room while preparing hazardous drugs. However, the standard offers an exclusion: in facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (two tier containment process within a BSC or CACI that is located in a non-negative pressure room) is acceptable. It is extremely important to note that Containment Technologies Group, Inc. has a two tier containment process defined within its policies and procedures and has had the low volume requirement within the MIC Isolator defined for many years. The low volume breakpoint within a MIC Isolator is 150 doses prepared per person per 8-hour shift. Any volume that is lower than this definition is acceptable within the MIC Isolator outside of a negative pressure room.

In conclusion, every Containment Technologies Group, Inc. client (as well as potential client) has received a very comprehensive documentation package with validated data that proves without a shadow of a doubt every statement made within this letter. In fact, our documentation package proves several other key issues such as there is no need to vent the MIC Isolator and there is no need to be fully garbed while using the MIC Isolator. We greatly appreciate your interest in our MIC Family of Products and encourage you to contact your local sales representative or our home office if you have any further questions.

Sincerely,

Containment Technologies Group, Inc.