The University of Iowa Dezii Translational Vision Research Group

TITLE: Sterile Products Room Classifications

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A. OBJECTIVE

To define the Sterile Products room classifications and minimum room pressure differentials.

B. APPLICABILITY

The following is to be monitored by Sterile Products personnel.

C. REFERENCES

International Standardization Organization – ISO
D-DEZ-PRO-025 Setup and Cleaning of the Clean Room
D-DEZ-PRO-028 Aseptic Technique in a Clean Room

D. ROOM CLASSIFICATIONS

1. ISO 5 Areas

Clean Room Processing Room West (L174Pw) surrounding the BioSpherix Xvivo Unit #1,

Clean Room Processing Room East (L174Pe) surrounding the BioSpherix Xvivo Unit #2,

2. ISO 6 Rooms

Gowning Room West - L174Gw

Gowning Room East - L174Ge

Material Staging Area - L174M

3. Unclassified Rooms

Equipment room L174E

Service chase L174S

E. ROOM PRESSURE DIFFERENTIALS

1. ISO 5 Area Pressure Differentials:

L174Pw to L174Gw - a minimum of 0.05 inches with a target of 0.07 inches.

L174Pe to L174Ge - a minimum of 0.05 inches with a target of 0.07 inches.

2. ISO 6 Pressure Differentials:

L174Gw to L174M - a minimum of 0.05 inches with a target of 0.07 inches.

L174Ge to L174M - a minimum of 0.05 inches with a target of 0.07 inches.

L174M to L174E - a minimum of 0.05 inches with a target of 0.13 inches.

L174M to L174S - a minimum of 0.05 inches with a target of 0.13 inches.

F. History

Effective Date	Revision	Change
8 Aug 2015	0	Original document