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CLEANROOM PARTICLE SHEDDING ANALYSIS REPORT

REPORT #C19262ML

STANLEY

ProCare 8300A Automatic Sliding ICU Isolation Room Door with UL 1784 / NFPA 105 Leakage Rating for Smoke and Draft, Isolation Seals, Positive Latching, and Electric Strike.

SEPTEMBER 2019

By

OMNI TESTING, LTD.

I. ABSTRACT

The STANLEY ProCare 8300A Automatic Sliding ICU Isolation Room Door underwent particulate shedding testing for use in a cleanroom environment. The door experienced approximately 11 hours of continuous, automatic operation. During operation, the shed particulate was compared to cleanroom background shed particulate concentrations at eight discrete size thresholds. As a result of the testing, the ProCare 8300A Automatic Sliding ICU Isolation Room Door is suitable for use in all cleanrooms classified under Federal Standard 209E – Imperial or Metric as well as for any room classified as ISO 14644-1: 2015 Class 4.5.

II. INTRODUCTION

OMNI TESTING LTD, Swampscott, MA, was selected by STANLEY Access Technologies to conduct particle shedding and cleanroom compatibility testing of its ProCare 8300A Automatic Sliding ICU Isolation Room Door. OMNI TESTING, LTD. maintains a 12'8" x 8'4" x 7'11" high, open plenum supply, perforated raised floor, vertical unidirectional flow cleanroom in its Swampscott, MA facility. The room is capable of performing cleaner than ISO 14644-1:2015 – Class 1.5 at a 0.1 µm particle size.

STANLEY provided a fully functional, reduced-size, 2-leaf, sample door, of approximately 81" long and 48" high complete with a fully operable drive mechanism, and local control system. The door was center-positioned inside of the cleanroom and framed with (2) tubular steel, A-frame supports. The OMNI testing technician could operate the door with an IR remote push-button opening switch while remaining out of the way of both sampling air stream and the door installation. The remote switch allows the door to cycle repeatedly. The OMNI test technician was not present in the room during either the background or operating testing. The door was delivered by STANLEY and set up and installed by STANLEY personnel in the Swampscott, MA facility. Unpacking, installation, and preliminary 70% I.P.A. cleaning required approximately 90 minutes, accomplished on 05SEP19.

OMNI TESTING personnel were responsible for cleaning the door with non-linting wipes, 70% Isopropyl Alcohol and removing any hard-to-reach dust with CRC aerosol spray can electronics cleaner for inaccessible portions of the operator section. The testing was conducted over four days, beginning Monday, 09SEP19 and finishing Thursday, 12SEP19. No client representatives were on-site during the independent testing. Cleanroom background particulate levels were monitored before the door assessment on 09SEP19. All instrumentation used in the analysis of both the cleanroom and door were in current N.I.S.T. calibration. One, 8-channel, TSI particle counter, with sampling capability of particle sizes ranging from 0.10 µm up to 5 µm was utilized to measure the door particulate shedding. Reported

data is at all sizes between 0.1 µm and 5 µm size ranges. The conclusions and results are all based on all sizes, with special attention paid to the 0.5 µm size.

Background particulate sampling was accomplished at 42" above the finished floor. Thirty-one, distinct, 10.0-minute, 1.0 CFM, (0.283M^3), background samples were taken at the 42" A.F.F. elevation. To facilitate capture of any shed particulate, a 12" x 15" GORPLER™ aerosol sampling array was utilized which covers a relatively broad area (~ 1.25FT^2) to avoid missing particulate traveling in the vertical streamlines of the unidirectional flow air-stream. Once the background sampling was complete, the active door sampling took place at two locations, location #1 at the latch end of the sliding leaf, 6" above the finished floor, and location #2 at the opposite end of the door below the motor and drive mechanism, also 6" A.F.F. The drive mechanism was a STANLEY DURA-GLIDE™ OPERATOR. The GORPLER™ was manually relocated by the OMNI test technician from location #1 to # 2, in between active sampling. Locations are shown in figure #3. Figure #1 below details the sampling schedule.

Fig 1. Sampling Schedule

CONDITION	Samples	Time per Sample (min)	Volume per Sample (M^3)	Total Sample Volume (M^3)	Total Sample Time (min)	Door Cycles
Background	31	10	0.283	8.77	310	0
Location 1	38	10	0.283	10.75	380	2,111
Location 2	18	10	0.283	5.09	180	1,000

Overall, including background and operating sample testing, 869 FT^3 (24.6 M^3) of clean air was sampled in conducting this analysis.

III. SETUP

Figure #2 shows the cleanroom vertical, unidirectional velocities in feet per minute (fpm) taken 6" from the ceiling, egg-crate acrylic diffusers. The average velocity of the cleanroom was 107 fpm during the test. The cleanroom velocity test was conducted on 09SEP19.

Figure 2. Cleanroom Air Velocities (fpm)

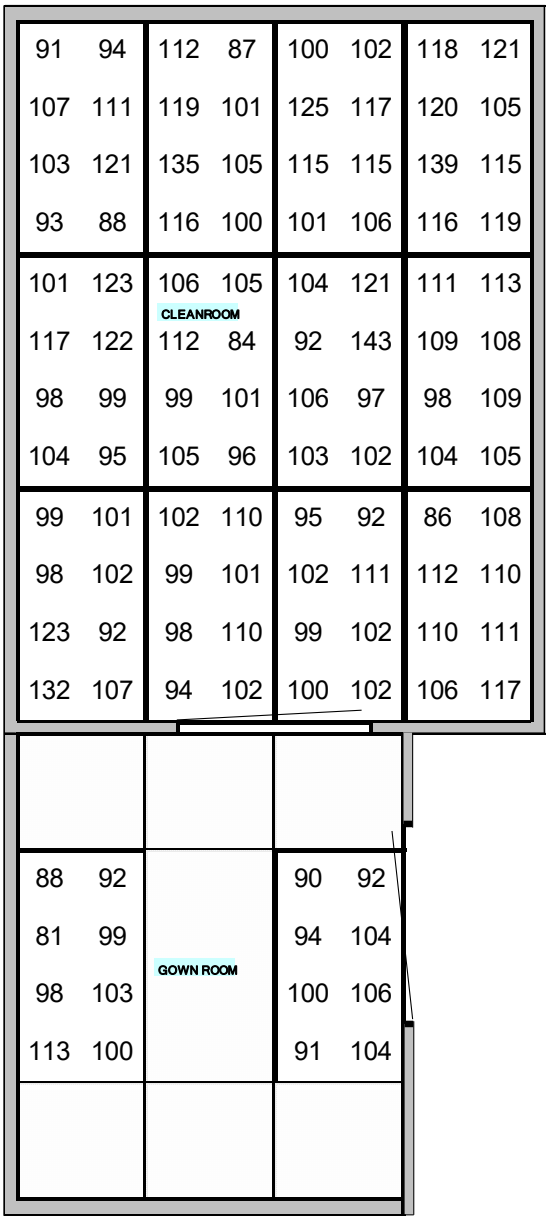
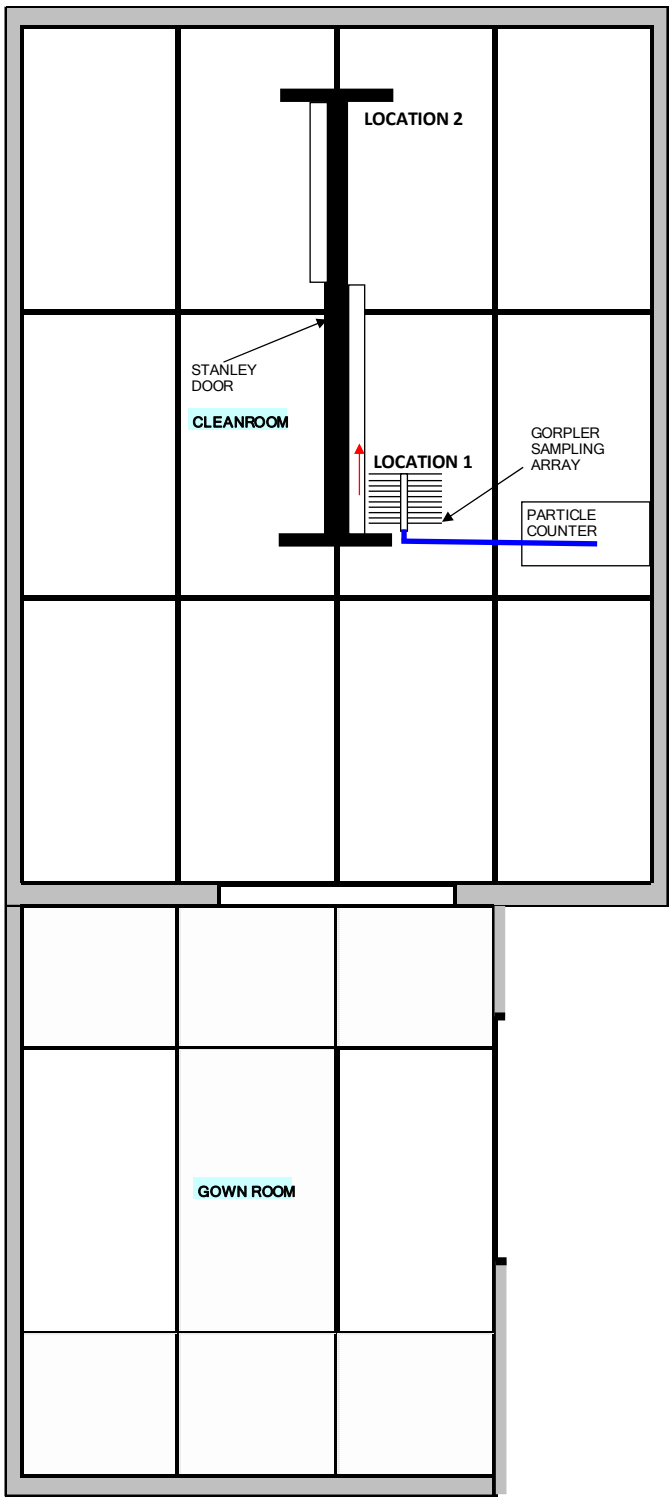


Figure #3 shows the GORPLER sampling setup relative to the door and cleanroom position.

Figure 3. Sampling Configuration



The door had been set up by STANLEY personnel to have an approximate 10.8 second cycle time, with a 4.0 second opening time, 1.4-second hold-open, a 4.0 second closing time, and a 1.4-second hold-close. The total travel of the sliding leaf was 37". The average travel speed was consequently 9 inches/sec

upon opening and closing. A TSI particle counter having a 1.0 CFM sampling rate and connected to the GORPLER™ sampling array, having 60 precision-bore sampling points over the 1.25 ft^2 sampling area, was utilized for both the background and door-operating data gathering. Instrumentation specifics can be found in the Instrumentation Calibration section of this report.

Figure 4. ProCare 8300A Automatic Sliding ICU Isolation Room Door Setup

IV. DESCRIPTION PROTOCOL

Before beginning any sampling, an initial cleaning of the door & installation was conducted with 70% IPA and cleanroom wipes. The glazing was cleaned with an ammonia-based glass cleaner. The aluminum frame was wiped down with moist cleanroom wipes.

The particle count data for the background efforts and 2, discrete, door-operating locations trials are individually presented in the following section. The raw data sheets show particulate data for all eight size channels. The analysis was conducted at one -parameter, the Average (X). For convenience, classifications were conducted and calculated according to 3 standards: ISO 14644-1:2015, Federal Standard 209E (Metric) and Federal Standard 209E (Imperial), the latter two being presently obsolete.

A chart (Figure #10) is presented at the end of the Presentation of Data section of this report illustrating the OMNI background cleanroom and the STANLEY ProCare 8300A Automatic Sliding ICU Isolation Room Door contribution shown against the recognized ISO 14644-1:2015 classifications.

V. PRESENTATION OF DATA

Figure 5. Background Particle Concentrations

		Particles per Cubic Meter							
		0.10	**0.15**	**0.20**	**0.25**	**0.30**	**0.50**	**1.00**	**5.00**
Sample Number		µm	µm	µm	µm	µm	µm	µm	µm
1	BACKGND	28	11	4	4	0	0	0	0
2	BACKGND	42	18	11	4	0	0	0	0
3	BACKGND	18	7	4	0	0	0	0	0
4	BACKGND	49	21	14	11	7	4	4	4
5	BACKGND	35	21	11	7	4	0	0	0
6	BACKGND	28	7	0	0	0	0	0	0
7	BACKGND	35	14	11	4	0	0	0	0
8	BACKGND	25	11	7	4	0	0	0	0
9	BACKGND	32	18	11	11	4	0	0	0
10	BACKGND	21	11	0	0	0	0	0	0
11	BACKGND	18	7	4	4	0	0	0	0
12	BACKGND	21	14	4	4	4	0	0	0
13	BACKGND	85	46	0	0	0	0	0	0
14	BACKGND	18	7	7	4	0	0	0	0
15	BACKGND	14	0	0	0	0	0	0	0
16	BACKGND	25	14	11	7	0	0	0	0
17	BACKGND	25	7	4	4	4	0	0	0
18	BACKGND	21	11	7	4	0	0	0	0
19	BACKGND	39	21	4	4	0	0	0	0
20	BACKGND	11	11	0	0	0	0	0	0
21	BACKGND	28	25	7	0	0	0	0	0
22	BACKGND	18	7	7	7	4	0	0	0
23	BACKGND	7	0	0	0	0	0	0	0
24	BACKGND	7	4	0	0	0	0	0	0
25	BACKGND	32	14	4	4	0	0	0	0
26	BACKGND	7	4	0	0	0	0	0	0
27	BACKGND	11	7	7	0	0	0	0	0
28	BACKGND	11	11	4	0	0	0	0	0
29	BACKGND	25	21	11	7	7	7	7	7
30	BACKGND	11	0	0	0	0	0	0	0
31	BACKGND	25	18	7	0	0	0	0	0
AVERAGE		**24.83**	**12.42**	**5.01**	**2.85**	**1.03**	**0.34**	**0.34**	**0.34**

Figure 6. Location 1 Particle Concentrations

	Particles per Cubic Meter							
	0.1	**0.15**	**0.2**	**0.25**	**0.3**	**0.5**	**1**	**5**
LOCATION	µm	µm	µm	µm	µm	µm	µm	µm
1	21	18	11	11	11	11	11	11
1	11	7	4	4	0	0	0	0
1	113	35	0	0	0	0	0	0
1	32	25	21	18	18	18	14	14
1	35	21	7	7	7	7	4	4
1	18	14	7	7	7	7	7	7
1	7	4	4	4	4	4	4	4
1	32	7	4	4	4	4	0	0
1	18	11	4	4	4	4	0	0
1	35	35	25	21	21	11	11	11
1	11	4	4	4	4	4	4	4
1	42	42	42	42	39	4	4	0
1	7	0	0	0	0	0	0	0
1	11	11	4	4	4	4	4	0
1	49	25	0	0	0	0	0	0
1	21	11	7	7	7	7	7	7
1	7	7	7	7	7	7	7	4
1	25	11	7	4	4	4	4	4
1	7	7	7	7	4	4	4	0
1	53	21	18	14	11	0	0	0
1	124	99	78	71	64	39	32	25
1	113	78	57	46	42	32	21	14
1	106	88	71	57	46	21	21	14
1	71	46	39	39	25	14	4	0
1	67	42	42	25	21	7	7	4
1	71	39	28	25	18	11	7	7
1	99	85	67	67	53	39	18	0
1	78	42	28	21	21	7	7	7
1	81	67	39	32	28	7	0	0
1	74	46	39	32	28	18	14	7
1	78	57	39	35	32	18	11	0
1	11	7	4	4	0	0	0	0
1	46	21	11	11	4	4	4	4
1	42	14	0	0	0	0	0	0
1	25	11	7	0	0	0	0	0
1	67	42	7	7	0	0	0	0
1	39	14	11	7	0	0	0	0
1	42	28	21	7	0	0	0	0
AVERAGE	**47.02**	**30.02**	**20.17**	**17.10**	**14.03**	**8.18**	**5.95**	**3.90**

Figure 7. Location 2 Particle Concentrations

	Particles per Cubic Meter							
	0.1	**0.15**	**0.2**	**0.25**	**0.3**	**0.5**	**1**	**5**
LOCATION	µm	µm	µm	µm	µm	µm	µm	µm
2	21	11	7	4	0	0	0	0
2	11	4	4	0	0	0	0	0
2	14	11	4	4	0	0	0	0
2	25	11	7	0	0	0	0	0
2	11	0	0	0	0	0	0	0
2	57	35	14	4	0	0	0	0
2	25	11	4	0	0	0	0	0
2	18	4	4	0	0	0	0	0
2	21	14	7	4	0	0	0	0
2	7	4	0	0	0	0	0	0
2	11	11	7	4	0	0	0	0
2	11	7	4	4	0	0	0	0
2	35	7	7	7	4	0	0	0
2	14	4	0	0	0	0	0	0
2	32	18	7	4	4	0	0	0
2	18	11	11	0	0	0	0	0
2	18	11	0	0	0	0	0	0
2	28	14	14	4	0	0	0	0
AVERAGE	**20.80**	**10.20**	**5.49**	**1.96**	**0.39**	**0.00**	**0.00**	**0.00**

Figure 8. Average Net[1] Particle Contribution (Particles/m^3 ≥ size threshold)

	0.1µm	0.15 µm	0.20 µm	0.25 µm	0.30 µm	0.5 µm	1 µm	5 µm
LOCATION 1	22.19	17.60	15.15	14.25	13.01	7.84	5.61	3.56
LOCATION 2	-4.04	-2.22	0.48	-0.89	-0.63	-0.34	-0.34	-0.34

Figure 9. Calculated Iso 14644-1:2015 Class at Size Thresholds[2]

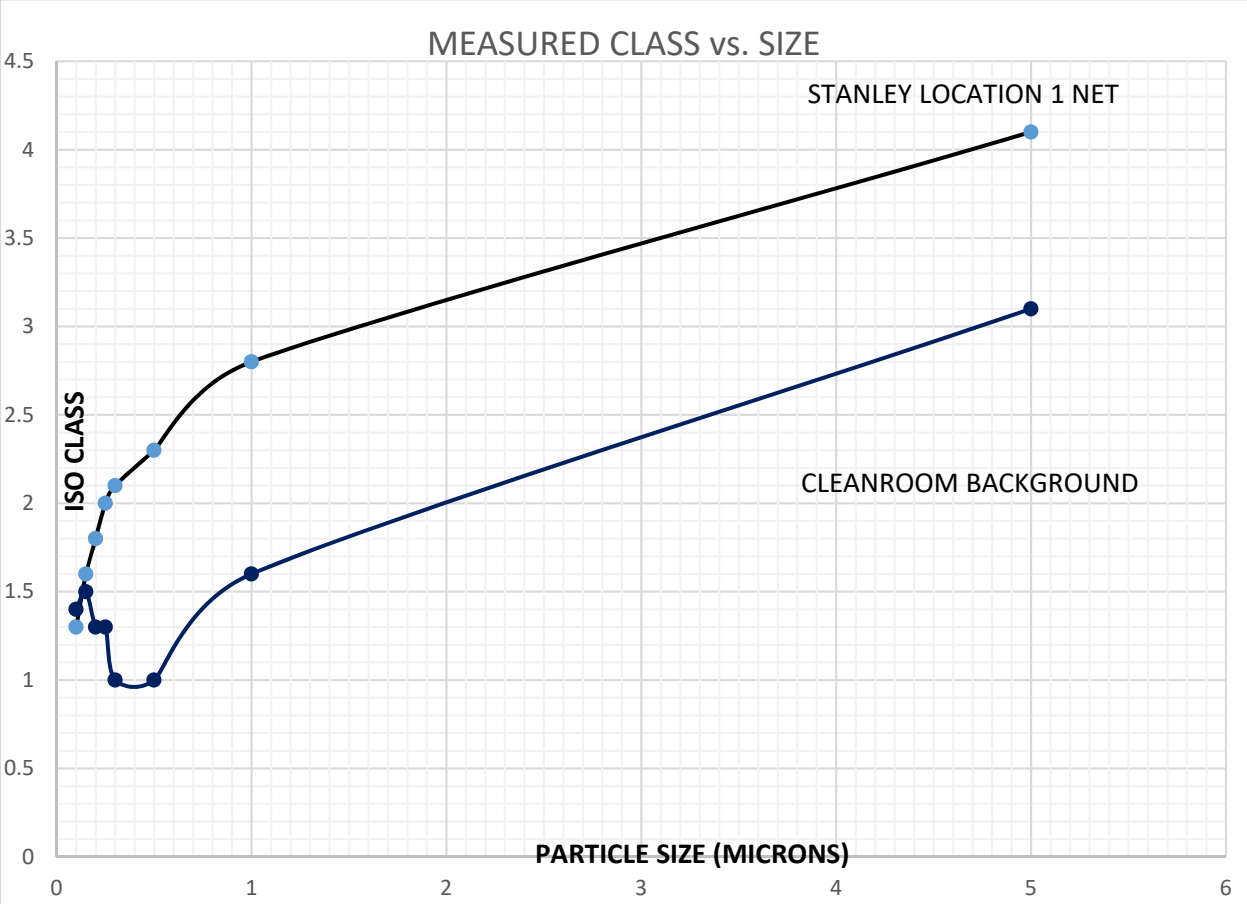
	0.1µm	0.15 µm	0.20 µm	0.25 µm	0.30 µm	0.5 µm	1 µm	5 µm
BACKGROUND	1.4	1.5	1.3	1.3	1.0	1.0	1.6	3.1
LOCATION 1	1.3	1.6	1.8	2.0	2.1	2.3	2.8	4.1

Location 2 was indistinguishable from background data; consequently, the analysis of the ProCare 8300A Automatic Sliding ICU Isolation Room Door is restricted to location 1, its worst-case condition. This phenomenon is likely due to two factors. First, the rubber door gasket makes contact

[1] Net values obtained by subtracting the average background values from the Location 1 data at each size threshold.
[2] This table of calculated values is based upon the strict theoretical calculation as given in equation 2. It does not recognize limitations imposed by sample volume as in equation 1 nor does it observe defined particle size thresholds or classification increments allowed by ISO 14644-1:2015, as it is intended for analysis only, and not formal classification.

with the inside of the latching jamb, is held for 1.4 seconds, and then is pulled away from the aluminum face of the jamb. Compression and adhesion of the gasket coupled with the extension of the gasket upon reopening likely contribute to particulate generation. Secondly, when the sliding leaf impacts the inside of the latching jamb and also when it is detached by the return action of the drive mechanism, causes system vibration which may release unstable particulate reservoirs.

Figure 10. Classification at Size Thresholds



VI. DATA ANALYSIS

Following ISO 14644-1:2015 or the now obsolete standard Federal Standard 209E, a sufficient statistical sample, adequate to capture 20 particles is necessary for classification.

Eq. 1. $Vs = \frac{20}{Cn}$; **V_s {C_n}**

Where V_s is the volume sampled (m^3), and C_n is the threshold limit for the desired classification at a chosen particle size (qty./m^3). The chosen sampling volume for the testing herein of 380 ft^3 is sufficient to demonstrate Classification as clean as ISO 14644-1:2015[3] Class 3.8 at 5 µm.

Eq. 2. $Cn = 10^N * \left(0.1/d\right)^{2.08}$; **C_n {N, d}**

Equation 2 shows the relationship between concentration threshold, C_n (qty. /m^3), ISO 14644-1:2015 classification designator, N, and size diameter, d, in microns. For example, a d = 0.1 µm particle size, at ISO Class N = 1, C_n =10 / m^3 or, approximately, 0.28/ft^3.

Equation #3 shows the relationship between concentration threshold, C_e, class designator, N_c, and particle diameter, d, in microns from the older, obsolete, Federal Standard 209E in British (Imperial) units of C_e = (qty./ft^3).

Eq. 3. $Ce = Nc * \left(\frac{0.5}{d}\right)^{2.2}$; **C_e {N_c, d}**

Where C_e is the number of particles per cubic foot and is equal to (C_n/35.3). N_c is the class designation (for instance Class 10,000 or Class 1,000, etc.) and d is the particle diameter in microns. The metric version of this relationship from Federal Standard 209E is expressed in equation 4.

[3] Calculated class, ISO 14644-1:2015 allows minimum class increments of half-integer.

Eq. 4. $Cn = 10^{M} * \left(\frac{0.5}{d} \right)^{2.2}$; **C_n {M, d}**

Where C_n, as before, is (qty. /m^3), M is the metric class designator (For example; Class M3.5, Class M5, etc.) and d is the particle diameter in microns.

The distinction between the various class designators, M, N_c, and N is crucial to understanding as it impacts the results in the conclusion section of the report.

Equations, 4, 5 & 6 show the interrelationships between the obsolete, Federal Standard 209E Metric, British-N_c, and the contemporary ISO 14644-1:2015 classifications, N.

Eq. 5. $Nc = \left(\frac{0.0010827 * 10^{N}}{\frac{1}{d}^{(3/25)}} \right)$; **N_c {N, d}**

Eq 6. $N = 0.43429 * \ln(923.653 * Nc) - 0.0521 * \ln(d)$ **; N {N_c, d}**

As a final comment, it should be noted that the range of cleanroom classifications between the older, obsolete, Federal Standard 209E (British) and the ISO 14644-1:2015 varies significantly. The lowest (British) class allowed under Federal Standard 209 was Class 1, N_c = 1. The lowest class allowed under ISO 14644-1:2015 is also Class 1; however, it is designated as N = 1.

As illustrated by Equation 5 above, an ISO 14644-1:2015 Class 1; (N=1, @ 0.1µm) would result in a hypothetical[4] Federal 209E Classification of Nc = 0.008 or more than 2 log scales below the minimum allowable class under the 209E standard.

The test data from the ProCare 8300A Automatic Sliding ICU Isolation Room Door

[4] Extrapolating outside of the allowable classifications is prohibited in conventional usage but is presented as a hypothetical for illustrative purposes.

shows that over 3,111 door opening cycles, the average concentration was 0.22 particles/ft^3 at the 0.5 µm size (1.59 particles/M^3). The data reveals that the STANLEY ProCare 8300A Automatic Sliding ICU Isolation Room Door did not contribute more than 0.22 particles/ft^3 at 0.5 µm (7.7/M^3).

VII. CONCLUSIONS

Based on the data collected, at the commonly- recognized size threshold of 0.5µm, the STANLEY ProCare 8300A Automatic Sliding ICU Isolation Room Door, when tested in a cleanroom environment cleaner than ISO 14644-1:2015 - Class 1.0, is cleaner than ISO 14644-1:2015 Class 2.5, and is suitable for any cleanroom classified under Federal Standard 209E – Imperial or Metric, at the 0.5 µm particle size, regardless of the cleanroom's classification. These would include any room serving the health care industry.

The STANLEY ProCare 8300A Automatic Sliding ICU Isolation Room Door is also suitable for any room classified as clean as ISO 14644-1:2015 Class 4.5, regardless of particle size.

VIII. INSTRUMENT CALIBRATION

Fig. 11 Instrumentation Schedule

PARAMETER	TYPE	MANUF	MODEL	SERIAL	CAL DATE	CAL DUE
VELOCITY	MULTIMETER	SHORTRIDGE	ADM-880C	M11028	10OCT18	10OCT19
PARTICLES	PARTICLE COUNTER	TSI	9110-01	91101718002	21JUN19	21JUN20

_____ DATE: 23SEP2019

Matthew C. Lemieux

FOR: OMNI TESTING, LTD.