NIOSH Expedient Isolation Research

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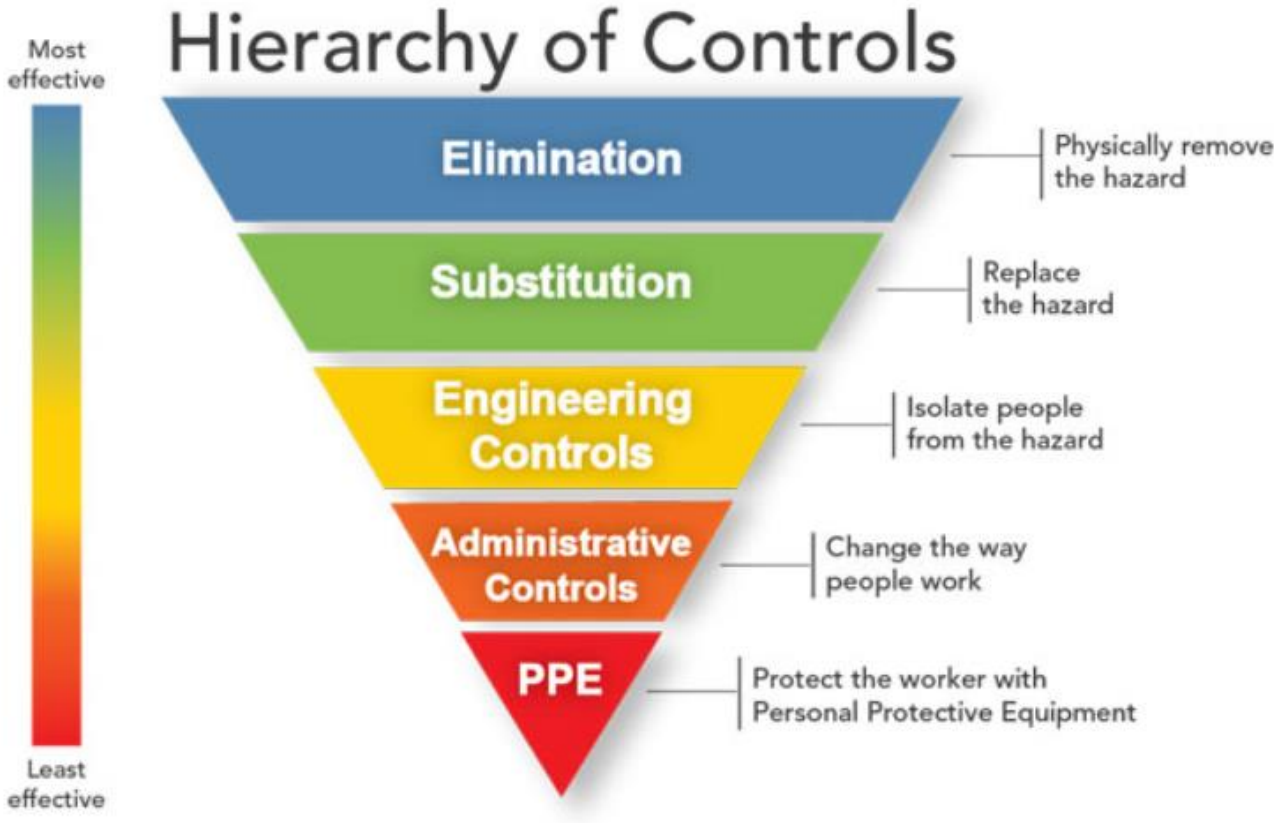
Toxicology Refresher (from an engineer!)

- Dose:
  - Airborne Dose = Airborne concentration x time x inhalation rate
  - Surface Contamination (from Infectious Aerosols):
    - ***f(x):*** **{**concentration, settling rates, and time between cleanings}
  - Common variables: **Concentration** & **Time**
- Today's discussion will focus on both the **Concentration** & **Time** variables.



Source: https://www.cdc.gov/niosh/topics/hierarchy/default.html

Airborne Infection Isolation Rooms (AIIRs)

- Dedicated single-patient room
- At least 12 air changes per hour (ACH) total ventilation (6 ACH if pre-2001), including min. 2 ACH outside air
- Maintained at negative pressure relative to adjacent areas (-0.01 inches water gauge, or 2.5 Pa)
- All seams & penetrations sealed
- All air exhausted to outdoors, (CDC: unless HEPA-filtered and returned to dedicated HVAC system)
- Portable High Efficiency Particulate Air (HEPA) fan/filter systems can be used to increase effective ACH of air cleaning

References: ASHRAE Standard 170, CDC 2005 TB Guidelines, CDC Environmental Infection Control Guidelines

The Problem

- Large hospitals typically have limited number of engineered AII rooms
- Small hospitals may have 1 engineered AII room
- There is essentially NO engineered surge capacity in case of epidemic (natural or intentional)
- Non-hospital medical, social service facilities, and health departments generally lack isolation capabilities

GAO Report/Testimony: April 2003

(A historical perspective?)

- Nation's capacity improved (since 09/11) but gaps in preparedness remain. Level of preparedness varied across jurisdictions.
- "..many hospitals lack capacity to respond to large scale infectious disease outbreaks."
- "..most hospitals lack adequate equipment, isolation facilities, and staff…"
- "…initial response to an outbreak of infectious disease would occur at the local level…"

Typical Surge Response Plans:

- Patient transfer
- Big-area iso (hot) zones with patient cohorting (worker unfriendly)
- Respirators and surgical masks with traditional patient rooms
- Shut patient room door and hope that existing dilution ventilation system is sufficient.
- Dilution Filtration with Portable HEPA units to achieve equivalent 12 ACH

ACH vs Clearance Time Determination

- Estimates wait time required to enter room for cleaning following occupancy by patient potentially generating infectious aerosols
- Affects room turnover wait period between patients
- AIIRs have significant waits – Non-AIIRs generally have longer waits

ACH vs Clearance Time Determination

1. Airborne Contaminant Removal

Table B.1. Air changes/hour (ACH) and time required for airborne-contaminant removal by efficiency *

ACH § ¶	Time (mins.) required for removal 99% efficiency	Time (mins.) required for removal 99.9% efficiency
2	138	207
4	69	104
6⁺	46	69
8	35	52
10⁺	28	41
12⁺	23	35
15⁺	18	28
20	14	21
50	6	8

* This table is revised from Table S3-1 in reference 4 and has been adapted from the formula for the rate of purging airborne contaminants presented in reference 1435.

Source: CDC Environmental Infection Control Guidelines (2003)

ACH vs Clearance Time Determination

(a closer look at the footnotes)

- Table B-1 Footnotes (2003 Infection Control Guidelines)
  - This table is revised from Table S3-1 in reference 4 and has been adapted from the formula for the rate of purging airborne contaminants presented in reference 1435
  - The times given assume perfect mixing of the air within the space (i.e., mixing factor = 1). However, perfect mixing usually does not occur. Removal times will be longer in rooms or areas with imperfect mixing or air stagnation. Caution should be exercised in using this table in such situations.

- Table S3-1 Footnotes (CDC's 1994 TB Guidelines)

  The times given assume perfect mixing of the air within the space (i.e., mixing factor = 1). However, perfect mixing usually does not occur, and the mixing factor could be as high as 10 if air distribution is very poor (98). The required time is derived by multiplying the appropriate time from the table by the mixing factor that has been determined for the booth or room.

Dilution Wait Times for Desired Removal Efficiency

ACH	Minutes Required for the Desired Removal Efficiency		
	90%	**99%**	**99.9%**
2	69	138	207
6	23	46	69
12	12	23	35

Assuming the aerosol source is stopped and a good dilution ventilation design (K=3), it will take 69 minutes (3 x 23) to achieve a 99% dilution of airborne particulate (assumes 100% of reduction is via dilution).

from one, for ideal mixing, to ten for poor mixing. As a rule of thumb, a mixing factor of three can be assumed for a room with 12 ACH and good air movement.).

$$C_2 = C_1 e^{-\left[\frac{Q\Delta t}{V}\right]}$$

$$\Delta t = -\left(\frac{V}{Q}\right)\ln(C_2 / C_1)$$

Expedient Isolation Research

Purpose: To evaluate portable filtration technology combined with increased levels of containment (as opposed to general room dilution) and directed airflows to provide expedient airborne isolation capability within healthcare settings not currently equipped for such isolation:

Basically looking for a cheap, easy, quick, yet effective "universal" method for reducing infectious aerosol concentrations and potential exposures to healthcare workers.

Researched Scenarios

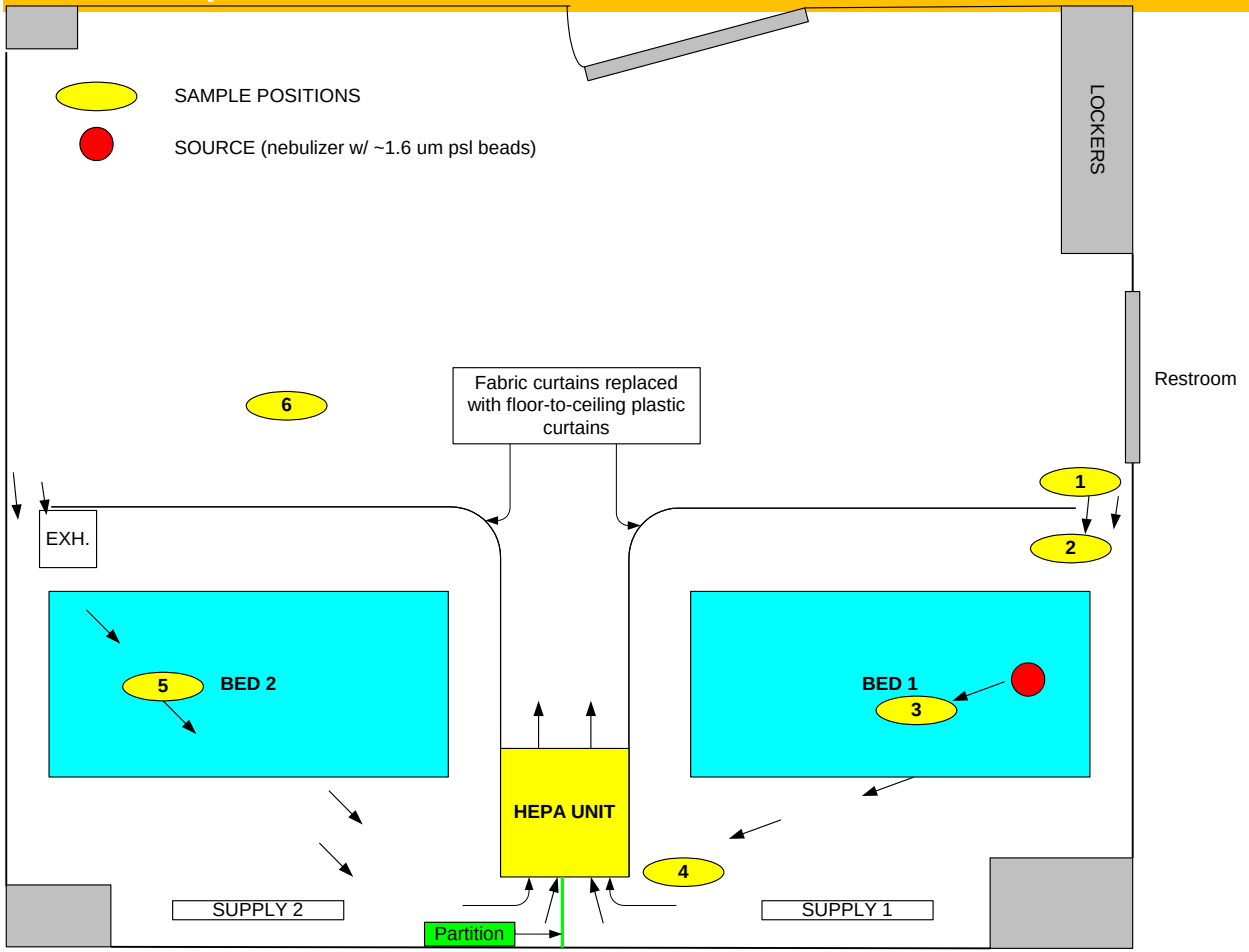
- Used portable HEPA filtration units like those already found in health care facilities

Photos Credited To: CDC/NIOSH

Portable Air Cleaners

- High efficiency particulate air (HEPA) fan/filter units
- HEPA = 99.97% efficient at 0.3 microns, even greater efficiency at other size ranges both smaller and larger than 0.3 microns.
- Human-generated infectious aerosol generally 1 um and larger.
- HEPA filtered air = clean outdoor air (from infectious aerosol perspective)
- Can also be used to augment Pressurization, Directional Airflow, and Direct Source Capture control techniques.

Expedient Isolation: Zone-within-Zone



Zone-within-Zone Test Conditions

1. A “no-control” condition without HEPA filtration or HVAC manipulation

2. A “control-on” condition with the HEPA system activated and the HVAC supply louvers left open (deflected)

3. Another “control-on” condition with the HEPA system activated and the HVAC supply louvers sealed closed

Alternative Approaches

- Reduce volume of contaminated zone (a.k.a. Zone-Within-Zone)
  - Effectively increases ACH w/in inner zone

Photo Credit: CDC/NIOSH

Qualitative Smoke Tests

- *Cumulus "Flow Checker" hand-held smoke generator (Photo Credit: Draeger)*

- *"Wizard Stick" toy*

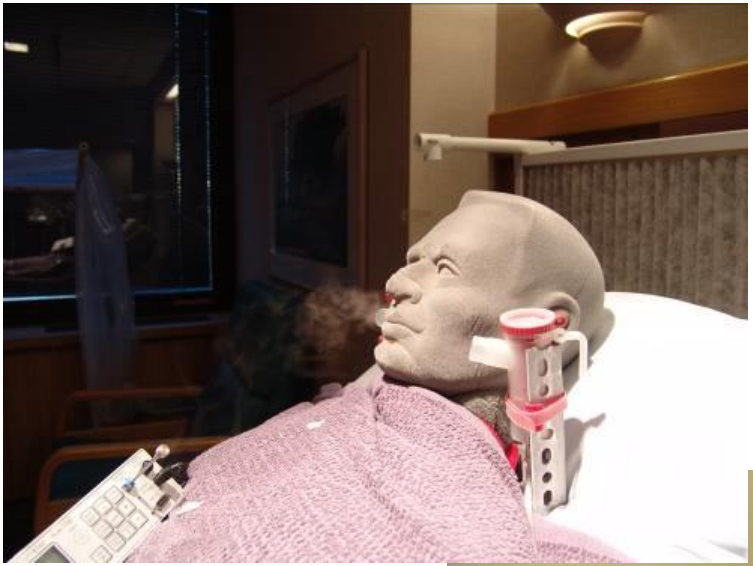
  (Photo Credit: www.teachersource.com)

Source (Aerosol) Generation

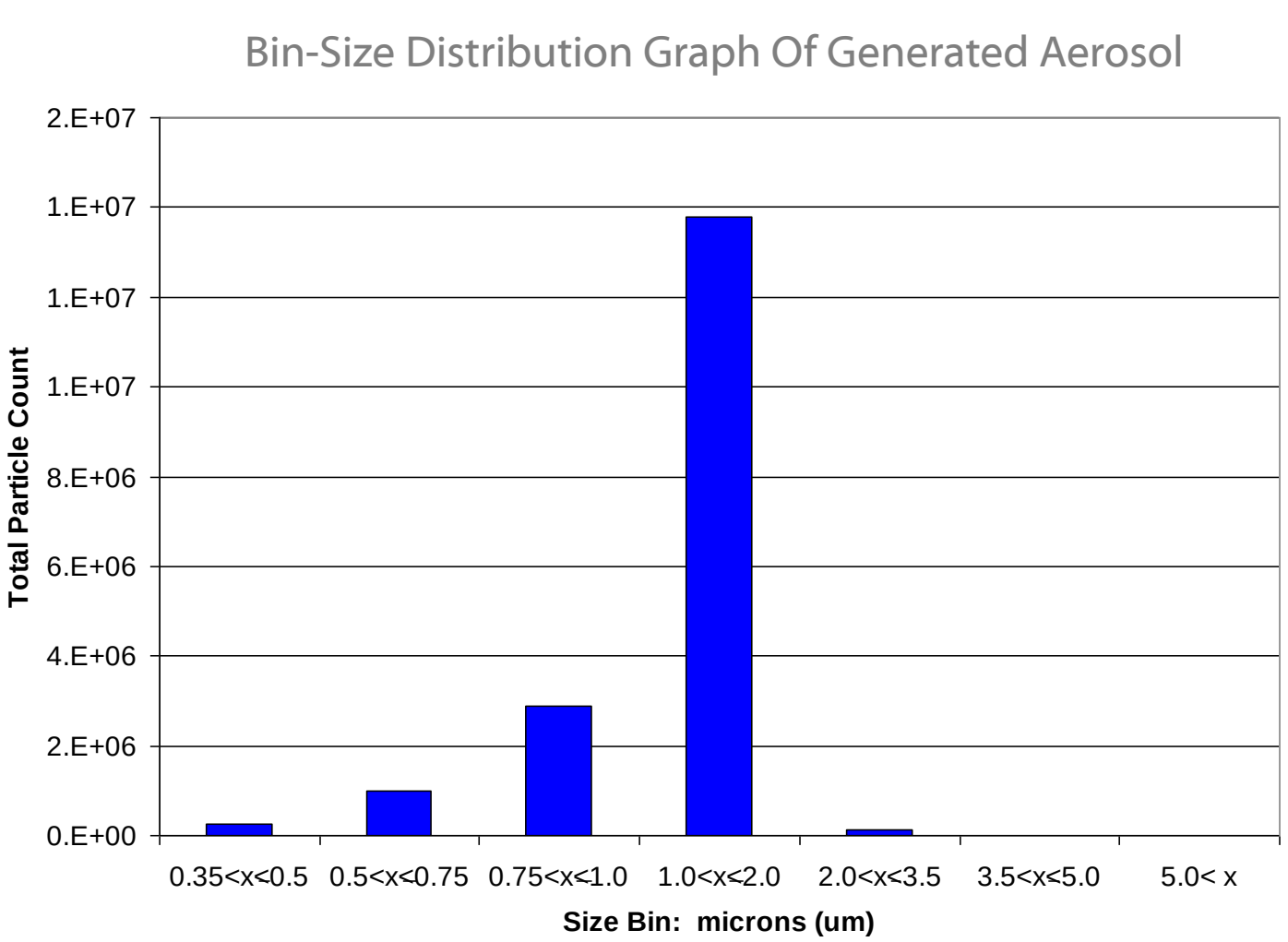
- ProNeb Ultra w/PARI LC Star Nebulizer (PARI Innovative Mani. Inc.)
- R.O. H_2O w/ 3 drops ~1.6 *um* polymer microspheres (Duke Scientific)

Photo Credit: CDC/NIOSH

Aerosol Generation/Measurement



Photos Credited to: CDC/NIOSH


Bin-Size Distribution Graph Of Generated Aerosol
Total Particle Count
2.E+07
1.E+07
1.E+07
1.E+07
8.E+06
6.E+06
4.E+06
2.E+06
0.E+00
0.35<x<0.5
0.5<x<0.75
0.75<x<1.0
1.0<x<2.0
2.0<x<3.5
3.5<x<5.0
5.0< x
Size Bin: microns (um)

Field Methodology

- The research was performed in multiple healthcare settings not currently engineered for airborne infectious isolation.

- Selected locations were two urban hospitals and two smaller, rural hospitals all within the states of Oklahoma and Kansas.

- Each facility received repetitive evaluations of the two expedient isolation design variations previously identified in the feasibility study.

Field Methodology

- Sought consistency with two key design and operational criteria currently applied to engineered airborne isolation rooms.
  - **Patient area**: Min. 100-120 sq-ft per patient.
  - **Volumetric flow rate**: Filtration flow rate (Q) sized to provide a minimum of 12 ACH within patient room (regardless of any smaller containment zone).

Analysis: Aerosol Spectrometer Data

- Wanted: Control-On to Control-Off Ratio count data
- The “control-on” test condition (conditions #2 and #3) data held much smaller particle (and right skewed) count values than those observed during the “control-off” condition (condition #1)
- Aerosol particle counts observed at the sample positions were log-transformed and the geometric means determined for the respective trials.
- The control-on conditions #2 and #3 were then compared with the uncontrolled condition #1 through a ratio of geometric means (gmean), which were presented in the form of:

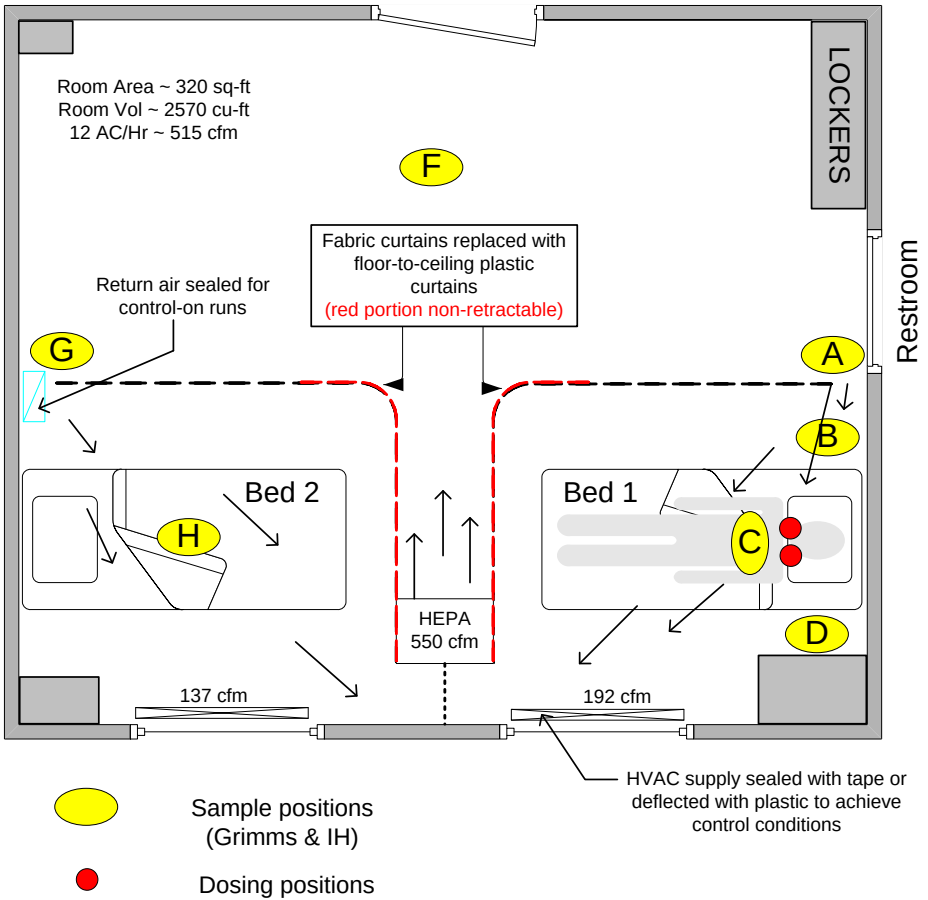
  Geometric Mean Reduction Ratio = (gmean1-gmeanx)/gmean1

  for x = 2, 3

- SAS Proc Mixed (SAS Version 9.13, SAS Institute Inc, Cary, NC) used to determine the 90 percent confidence limits on the geometric mean reduction ratio (GMRR).

Results

Expedient Isolation Configuration
VA Medical Center (VAMC), OKC, OK



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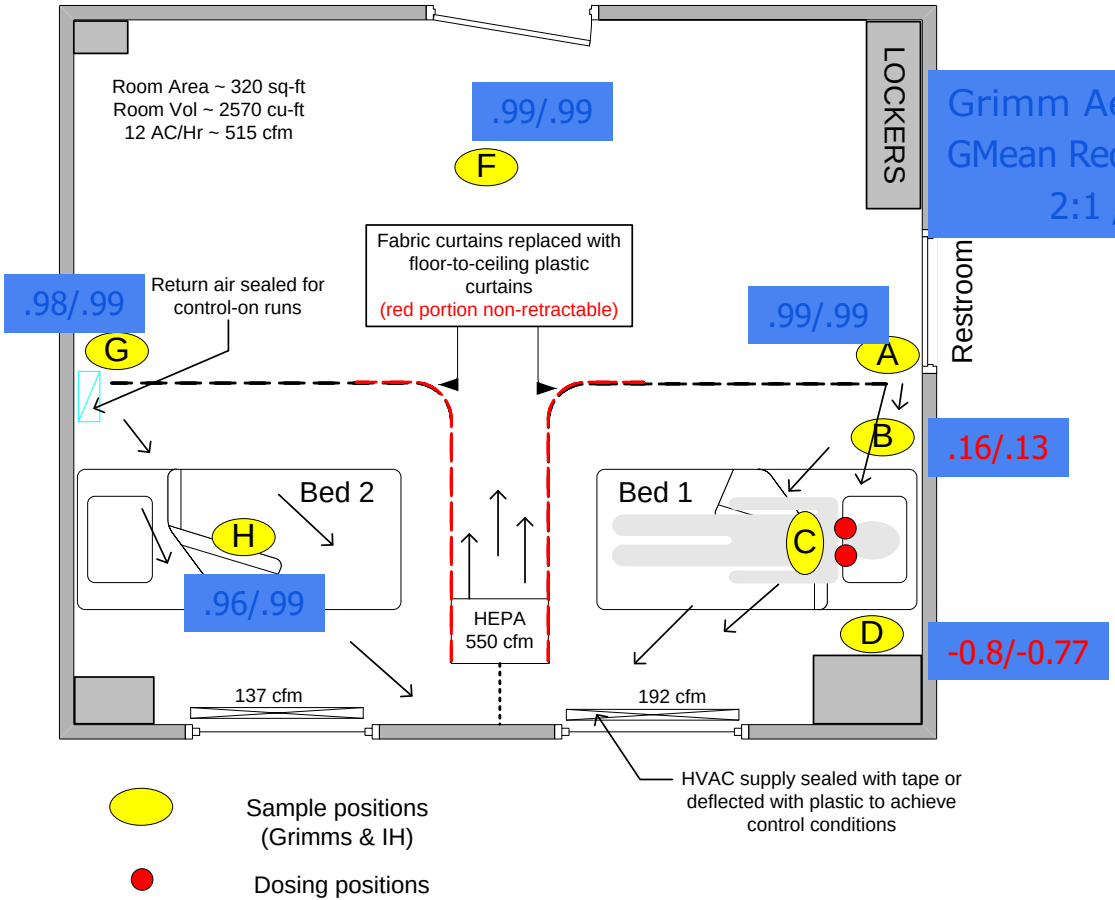
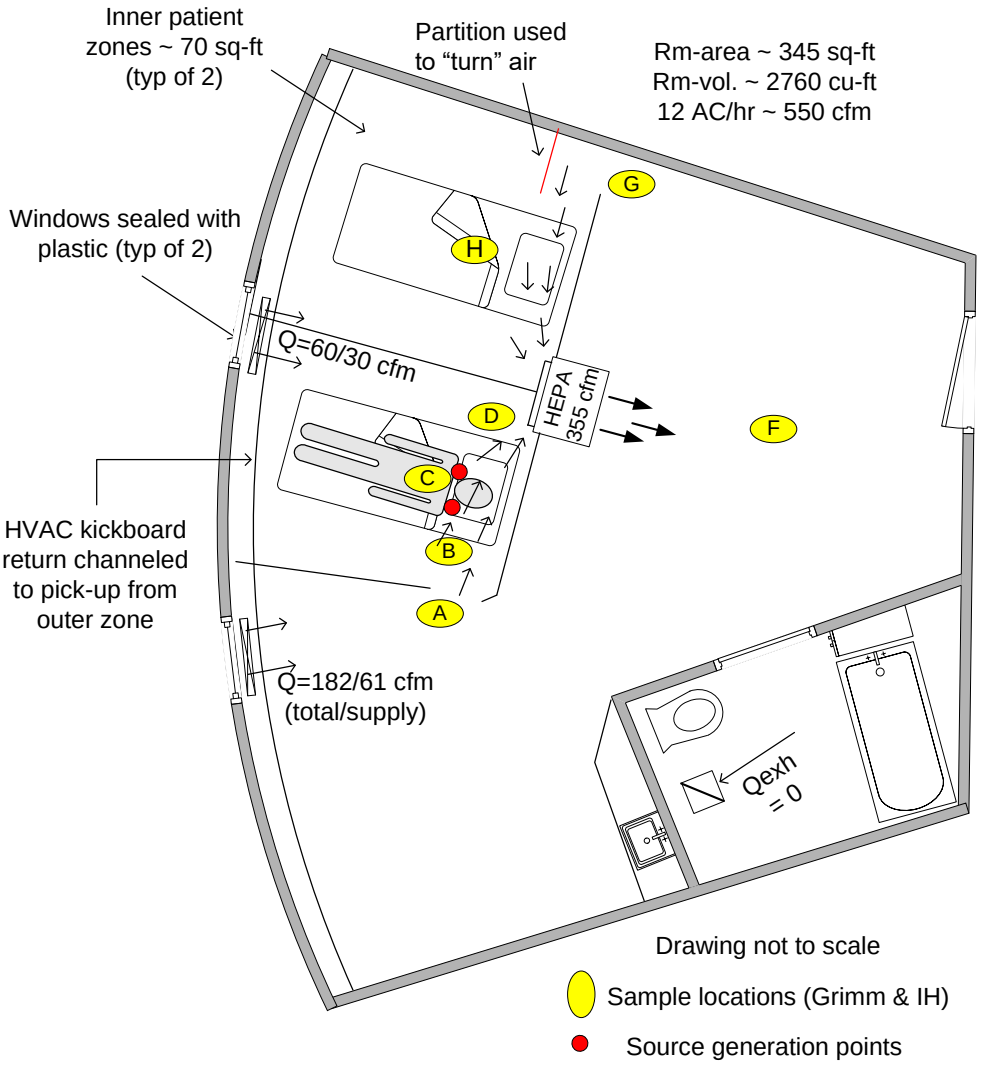
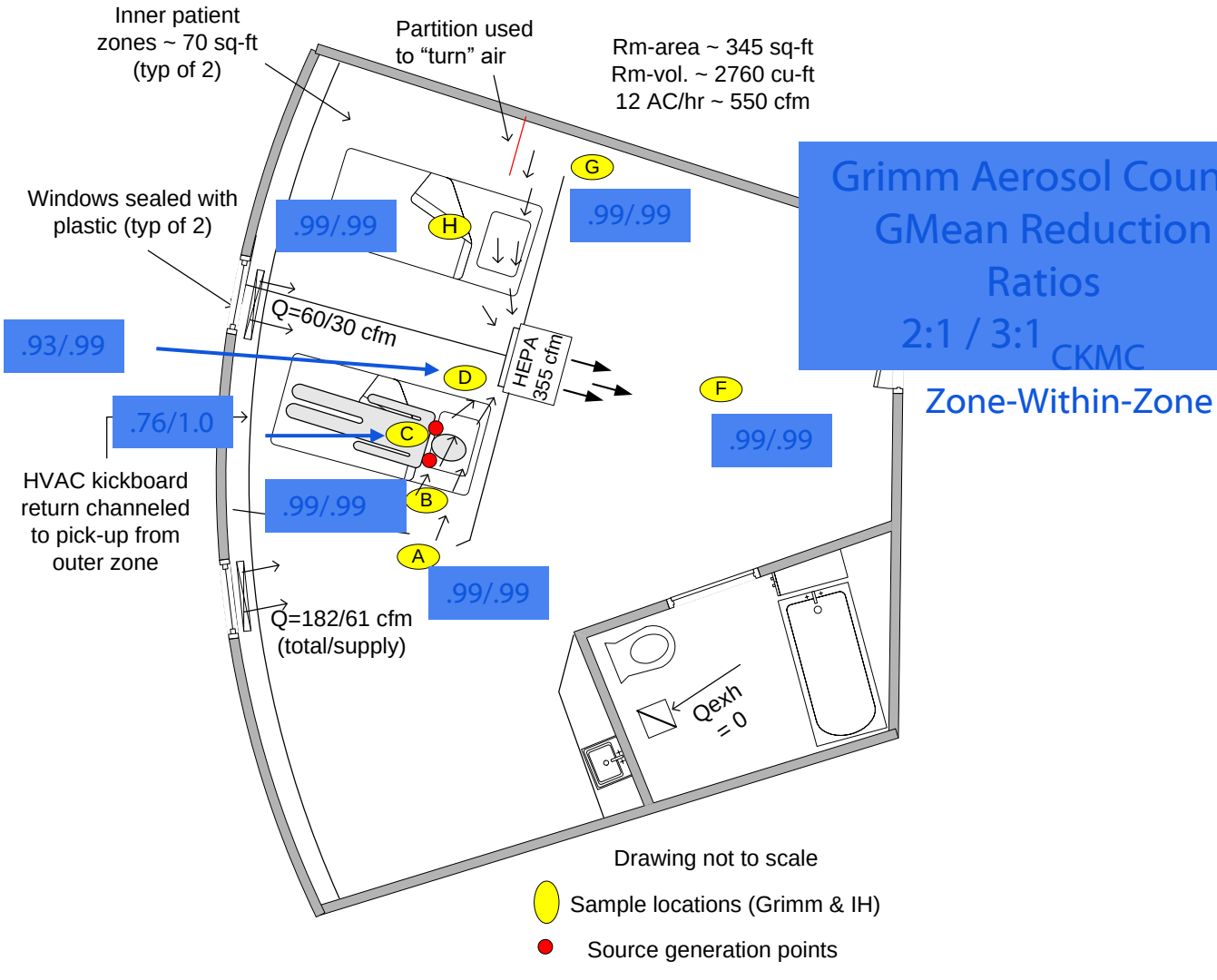


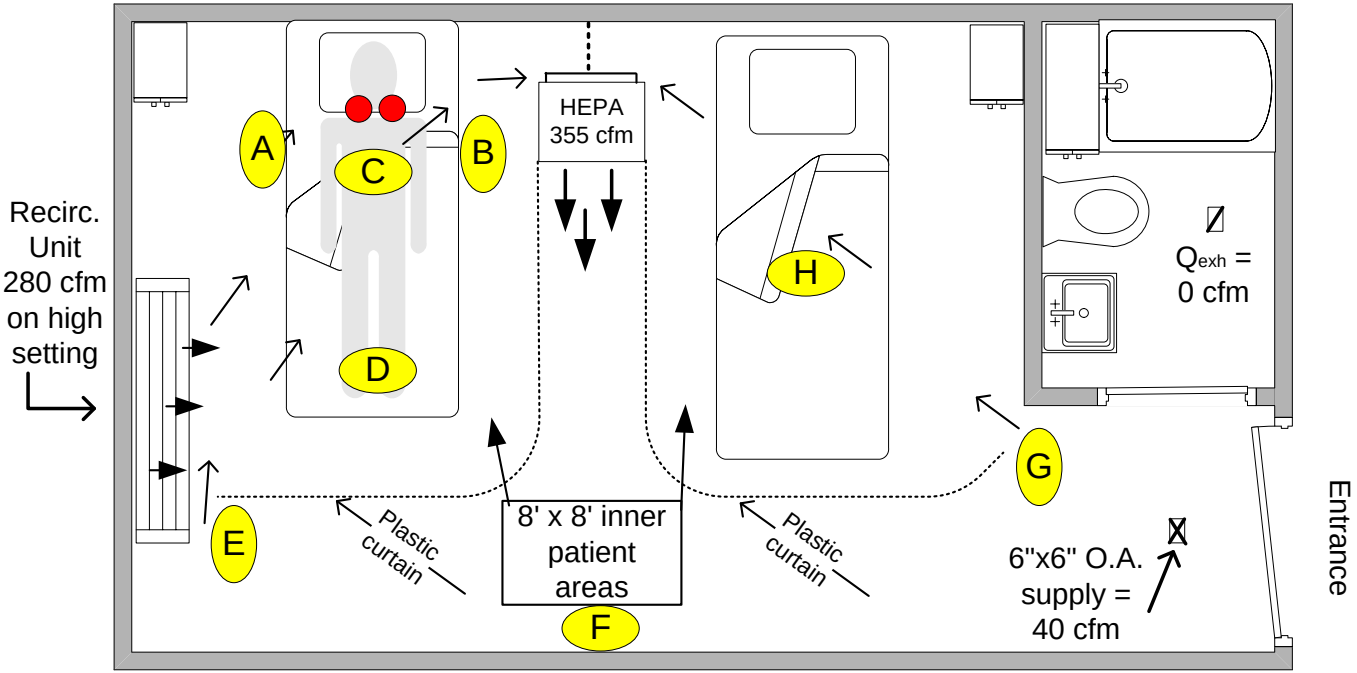


Zone-within-Zone:

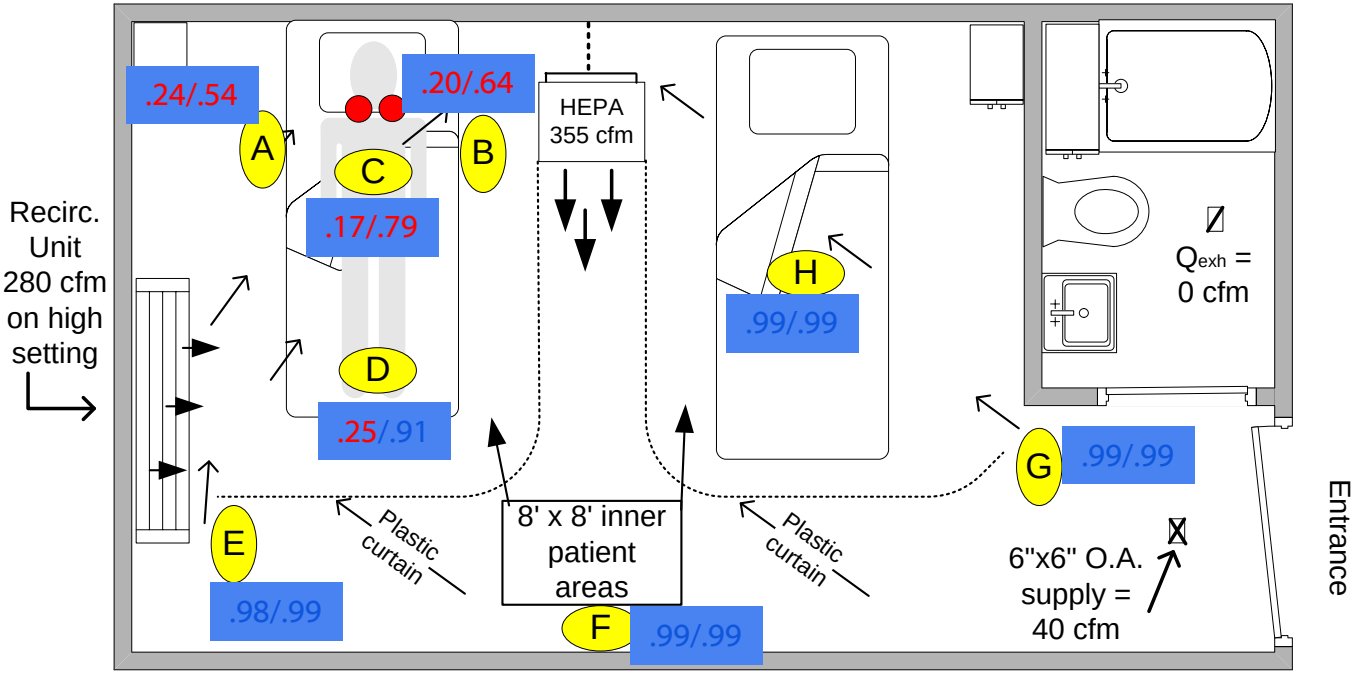
Central KS Medical Center (CKMC) Great Bend, KS


Inner patient zones ~ 70 sq-ft (typ of 2)
Partition used to “turn” air
Rm-area ~ 345 sq-ft
Rm-vol. ~ 2760 cu-ft
12 AC/hr ~ 550 cfm
Grimm Aerosol Counts
GMean Reduction Ratios
2:1 / 3:1
CKMC
Zone-Within-Zone
Windows sealed with plastic (typ of 2)
.99/.99
.99/.99
Q=60/30 cfm
.93/.99
HEPA 355 cfm
.76/1.0
.99/.99
HVAC kickboard return channeled to pick-up from outer zone
.99/.99
.99/.99
Q=182/61 cfm (total/supply)
Qexh = 0
G
H
D
C
B
A
F
Drawing not to scale
Sample locations (Grimm & IH)
Source generation points

Zone-within-Zone, ST Joseph Memorial Hospital (SJMH), Larned, KS



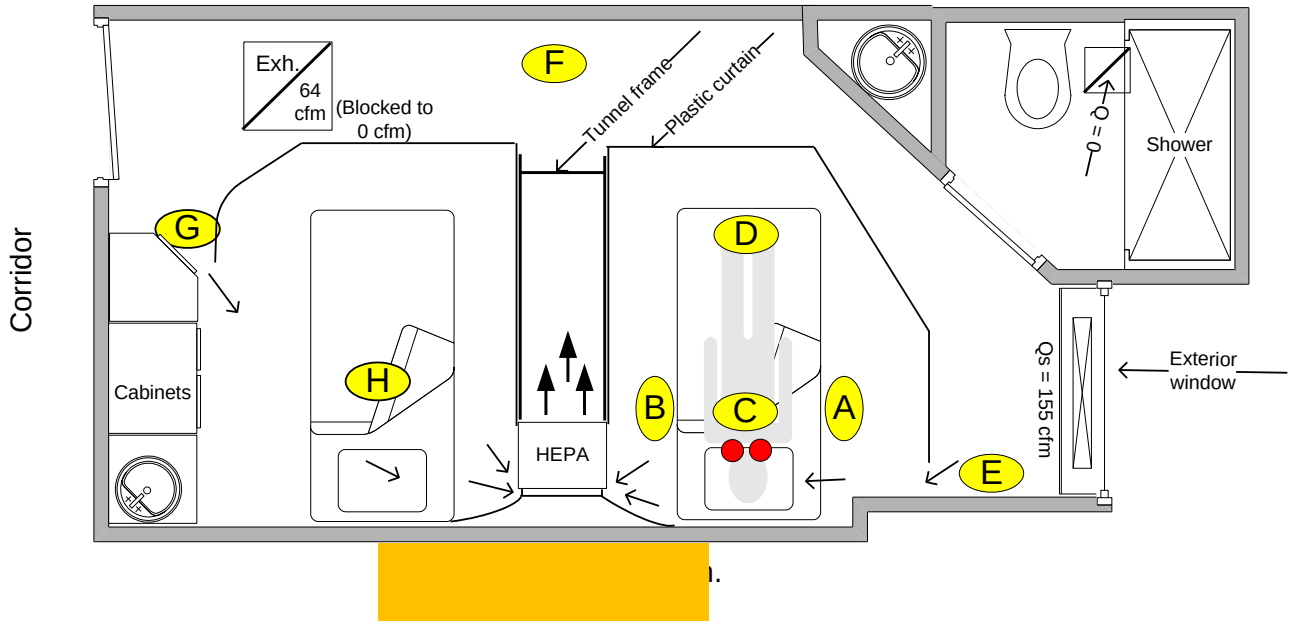
Zone-within-Zone, ST Joseph Memorial Hospital (SJMH), Larned, KS



Grimm Aerosol Counts
GMean Reduction

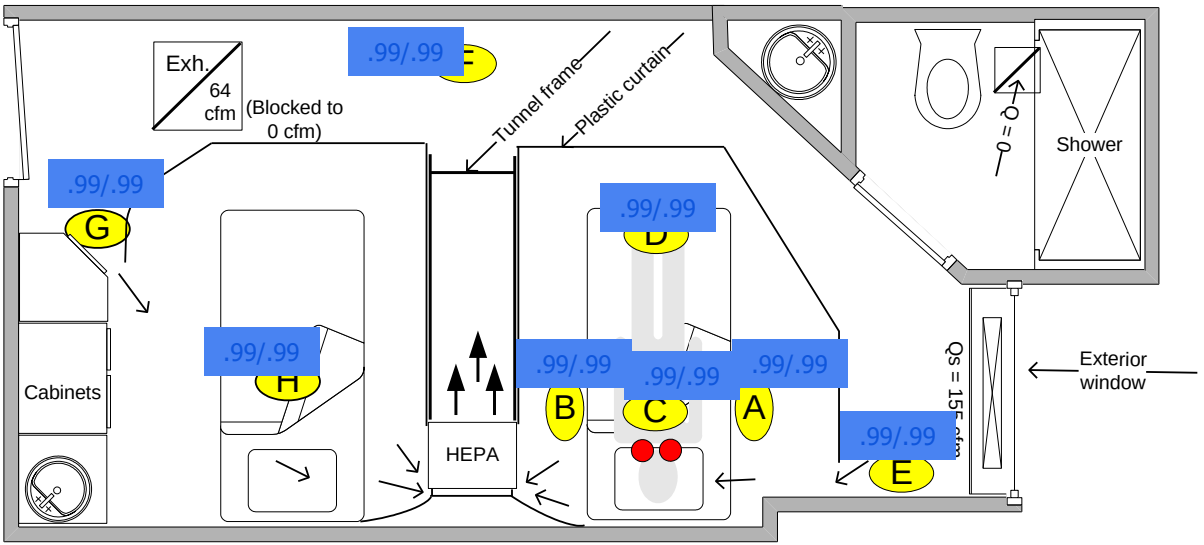
Integris Baptist Medical Center
Zone-within-Zone
OKC, OK

Rm 955, 2-Bed: Integris-Baptist OKC



Integris Baptist Medical Center
Zone-within-Zone
OKC, OK

Rm 955, 2-Bed: Integris-Baptist OKC



in.

Sample positions (Grimms & IH)

Dosing positions

Grimm Aerosol Counts
GMean Reduction Ratios
2:1 / 3:1

Summary of GMRRs and lower limits (in parentheses) for the Zone-Within-Zone (2-Bed) expedient isolation field studies, aerosol spectrometer data simultaneously–corrected for $\alpha = 0.10$ (Bold Red font = GMRR <90%)

Hospital / *Sample Pos.*	*VAMC* 2:1	*VAMC* 3:1	*CKMC* 2:1	*CKMC* 3:1	*SJMH* 2:1	*SJMH* 3:1	*IBMC* 2:1	*IBMC* 3:1
HCW-Upstream	**0.134** (**-4.10**)	**0.163** (**-5.65**)	0.998 (0.993)	0.993 (0.971)	**0.241** (**-0.536**)	**0.544** (**0.076**)	0.998 (0.986)	0.998 (0.989)
HCW-Downstream	**-0.767** (na)	**-0.800**	0.928 (na)	0.993	**0.204** (na)	**0.641**	0.996 (na)	0.999
Patient chest	na (na)		**0.761** (na)	1.00	**0.171** (na)	**0.791**	0.998 (na)	0.999
Patient feet	na (na)		na (na)		**0.247** (**-0.525**)	0.911 (**0.821**)	0.999 (0.994)	0.998 (0.991)
Outside Gap 1	0.998 (0.991)	0.999 (0.989)	0.998 (0.994)	0.993 (0.983)	0.984 (0.968)	0.991 (0.982)	0.998 (0.987)	0.998 (0.991)
Center Room	0.999 (0.994)	0.999 (0.991)	0.999 (0.996)	0.998 (0.996)	0.996 (0.992)	0.996 (0.992)	0.995 (0.970)	0.996 (0.979)
Outside Gap 2	0.993 (0.958)	0.997 (0.979)	0.999 (0.996)	0.999 (0.998)	0.988 (0.965)	0.997 (0.989)	0.998 (0.987)	0.997 (0.981)
Bed 2	0.987 (0.942)	0.997 (0.989)	0.999 (0.996)	0.996 (0.991)	0.987 (0.971)	0.991 (0.982)	0.998 (0.990)	0.996 (0.979)

Summary of GMRRs and lower limits (in parentheses) for the Zone-Within-Zone (2-Bed) expedient isolation field studies, aerosol spectrometer data simultaneously–corrected for $\alpha = 0.10$ (Bold Red font = GMRR <90%)

Hospital *Sample Pos.*	*VAMC* *2:1*	*3:1*	*CKMC* *2:1*	*3:1*	*SJMH* *2:1*	*3:1*	*IBMC* *2:1*	*3:1*
HCW-Upstream	**0.134** **(-4.10**	**0.163** **-5.65)**	0.998 (0.993	0.993 0.971)	**0.241** **(-0.536**	**0.544** **0.076)**	0.998 (0.986	0.998 0.989)
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Patient feet	na (na)		na (na)		**0.247** **(-0.525**	0.911 **0.821)**	0.999 (0.994	0.998 0.991)
Outside Gap 1	0.998 (0.991	0.999 0.989)	0.998 (0.994	0.993 0.983)	0.984 (0.968	0.991 0.982)	0.998 (0.987	0.998 0.991)
Center Room	0.999 (0.994	0.999 0.991)	0.999 (0.996	0.998 0.996)	0.996 (0.992	0.996 0.992)	0.995 (0.970	0.996 0.979)
Outside Gap 2	0.993 (0.958	0.997 0.979)	0.999 (0.996	0.999 0.998)	0.988 (0.965	0.997 0.989)	0.998 (0.987	0.997 0.981)
Bed 2	0.987 (0.942	0.997 0.989)	0.999 (0.996	0.996 0.991)	0.987 (0.971	0.991 0.982)	0.998 (0.990	0.996 0.979)

Discussion

- Containment Within Inner iso zones:
  GMRRs 98.4-99.9%+
  90% LCLs 94.2-99.8%
- Center-of-room results across all sites and configurations:
  GMRRs 99.5-99.9%
  90% LCLs 97-99.8%
- Worker exposure reductions (within inner iso zone) were more variable:

  -No meaningful exposure reductions (i.e. GMRR 90% LCLs <10%) associated with the two corner-to-corner/zone-within-zone configurations. However these areas still benefited from the increased dilution resulting (greater than 30 ACH) from the smaller isolation zone.

  - For side-to-side configuration, bedside worker exposure reductions were promising: GMRR: 92.8 - 99.9% + the increased dilution benefits.

Expedient Isolation Protection Factor (EIPF)

- A surrogate measure of the workplace protection
- Analogous to Simulated Workplace Protection Factor (SWPF)used by NIOSH in respirator testing.
- EIPF can be calculated by:

$$EIPF = \left(1 - GMRR\right)^{-1.0}$$

Expedient Isolation Protection Factor (EIPF)

Center Room Sample Results Across four study sites:

Mean EIPF = 364 (200-1000)*

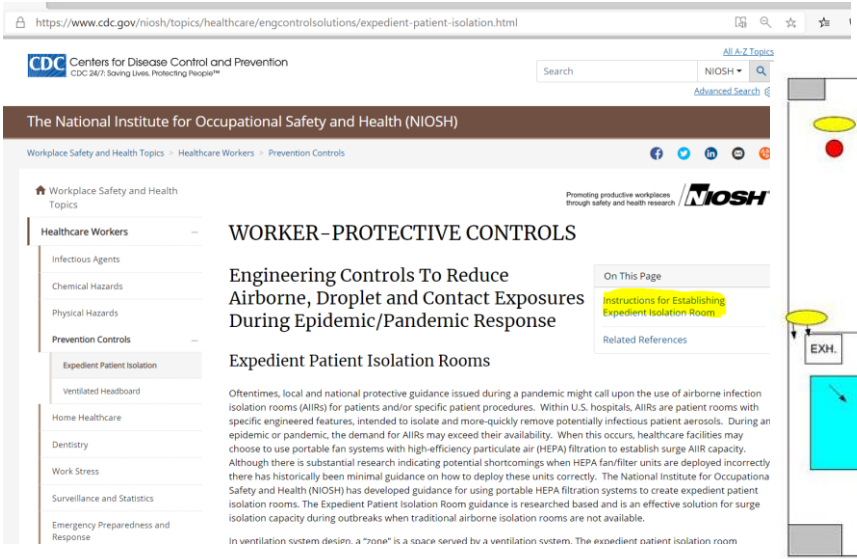
*20-100 times OSHA's N95 APF of 10

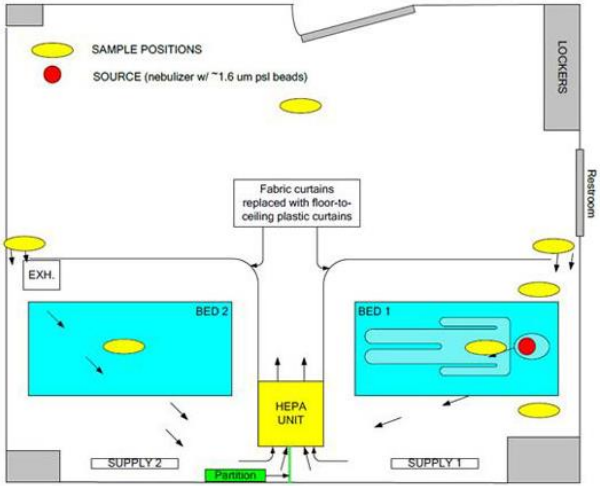
Research Conclusions

(https://www.cdc.gov/niosh/surveyreports/pdfs/301-05f.pdf)

- Current isolation guidance does not adequately address bioterrorism and epidemic response needs at the local level.
- Shortages of isolation capacity may impede the medical response to an emergency
- Current trends in surge iso design do not sufficiently address worker protection issues
- Expedient in-room isolation strategies employing high-flow HEPA filtration offer an alternative to emergency AII that is:
  - Affordable
  - Available
  - Effective
  - Fast to set up

NIOSH Webpage & Assembly Instructions





Source: CDC/NIOSH (https://www.cdc.gov/niosh/topics/healthcare/engcontrolsolutions/expedient-patient-isolation.html

Alternative Application: Protective ("Reverse") Isolation

CDC/NIOSH Photo Showing Ventilated Headboard Tested In Reverse Isolation Mode:

- Tested in this configuration following Japanese Tsunami & Fukushima Nuclear Incident.
- Emergency method for developing surge capacity in protective (reverse isolation) environments .
- Prescribed for patients who are immunosuppressed due to radiation exposure.
- Direction of filtered airflow is reversed from Airborne Infectious Isolation mode, providing positive pressure protective isolation.
- "Fit Test" protection factor > 15000
- ISO Class 5 Cleanroom Condition Under Hood (equivalent to that req'd for sterile pharmacy compounding)

Questions?

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For more information, contact CDC
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