[research / education] [vibration / acoustics] [construction research / education] [architecture & engineering]

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Buildings for Advanced Technology Workshop II
Mesa, Arizona

Risk Assessment and Mitigation in a User Environment

January 21, 2004

Nanotechnology – the Future?

"I know with absolute certainty that nanotechnology WILL change the world in ways it is still difficult to imagine."

Steve Forbes – Nanotech Report Investment Advisory

Nanotechnology – the Threat?

Can we conquer nanotech fear?

"The biggest alleged threat of nanotechnology is the **"grey goo"** scenario, in which billions of microscopic, self-replicating machines or "nano-robots" run amuck, deconstructing every atomic structure into a shapeless mush."

"Problems facing nanotechnologists include the fact that materials may exhibit different behavior at nanoscale, and the potential for **delayed negative reactions** from exposure to such substances."

Nanotechnology – the Threat?

Tackling such challenges will involve new techniques and a cross-disciplinary strategy. …… Nanotechnologists have come to realize the need for public accountability by seeing the detrimental effects of health scares and miscommunication on genetically modified food research and other scientific efforts. ….. scientists must participate in public debate so that a potentially crippling moratorium on nanotech research can be avoided. "We need to be seen as responsible, not as uncaring," he insists.

- Financial Times 1/15/04

Nanotechnology the Threat?

Excerpt from Michael Chrichton's PREY – nanotechnology based best seller …….

"….we've had a few accidents like that since I've been here. …. What kind of accidents? … they tried to make these buildings perfect, .. Because they're working with such small-size things. But it's not a perfect world, .. Never has been, never will be. …."

"… Contractor never balanced the air handlers right. We had 'em back five times to fix it, but this passage is always hot."

Nanotechnology the Challenges

What can be learned from the semiconductor industry ?

Nanotechnology the Challenges

What can we learn from ....

- Acid spill causes $50+ MM damage and extended production shut-down
- Fire causes $500 MM damage and 2 year shut down
- 250 employees sue manufacturer **alleging** their health was knowingly injured by chemical exposure from their jobs – dating back as long as 40 years ago!

Personnel Protection & Risk Management

The Issues: Research Needs/Drivers:

- Protection of Researcher Health and Welfare in a "User" Environment
- Effect of User Turnover, Visiting Researchers, etc.
- "B" vs. "H" Occupancy Considerations

Personnel Protection & Risk Management

The Issues: Research Needs/Drivers:

- Protection of Researcher Health and Welfare in a "User" Environment
  - User operations and activities are less well defined than in a manufacturing facility
  - Lack of repeatable and predictable activity creates challenges for EHS staff responsible for Health and Welfare
  - Necessary spontaneity of activity challenges EHS systems
  - Necessary range of chemicals challenges the audit and enforcement process
  - Unknown nature of research byproducts challenges the air and wastewater abatement systems
  - Somewhat unpredictable nature of operations challenges the Authorities Having Jurisdiction

Personnel Protection & Risk Management

The Issues: Research Needs/Drivers:

- Effect of User Turnover, Visiting Researchers, etc.
  - Training of users in local safety practices may be shortcut
  - User knowledge of emergency procedures may be limited
  - User knowledge of acceptable combinations of chemical challenges to air and wastewater systems may be limited
  - User knowledge of reporting requirements may be limited
  - I just made this, it didn't work out, how do I dispose of it?
  - "Rental car" mentality may exist – **why take care of this?, it's just a rental car ….**

The Issues: Research Needs/Drivers:

- "B" vs. "H" Occupancy Considerations
  - Identifying and quantifying hazardous materials may be very difficult
  - Maintaining an accurate audit of Haz Mats may be difficult to impossible
  - Transportation of Haz Mats must be carefully considered
  - Storage and treatment of waste products must be carefully considered
  - Deciding when the "exempt amount" threshold or maximum quantity threshold is reached may be a philosophical decision – in other words, if it looks like and acts like one, is it an "H" occupancy? and if so, which one?

Physical Hazards

TABLE 3-D - EXEMPT AMOUNTS OF HAZARDOUS MATERIALS PRESENTING A PHYSICAL HAZARD
MAXIMUM QUANTITIES PER CONTROL AREA[1a]

CONDITION		STORAGE[2]			USE[2]-CLOSED SYSTEMS			USE[2]-OPEN SYSTEMS	
MATERIAL	CLASS	Solid Lbs.[3] (Cu. Ft.) x 0.4536 -kg x 0.0283-m³	Liquid Gallons[3] (Lbs.) x 3.785 - L x 0.4536 -kg	Gas Cu. Ft. x 0.0283-m³	Solid Lbs. (Cu. Ft.) x 0.4536-kg x 0.0283-m³	Liquid Gallons (Lbs.) x 3.785-L x 0.4536-kg	Gas Cu. Ft. x 0.0283-m³	Solid Lbs. (Cu. Ft.) x 0.4536 - kg x 0.0283-m³	Liquid Gallons (Lbs.) x 3.785 - L x 0.4536-kg
1.1 Combustible Liquid[4,5,6,7,8,9]	II	N.A.	120[10]	N.A.	N.A.	120	N.A.	N.A.	30
	III-A	N.A.	330[10]	N.A.	N.A.	330	N.A.	N.A.	80
	III-B	N.A.	13,200[10,11]	N.A.	N.A.	13,200[11]	N.A.	N.A.	3,300[11]
1.2 Combustible Fiber (loose) (baled)		(100) (1,000)	N.A. N.A.	N.A. N.A.	(100) (1,000)	N.A. N.A.	N.A. N.A.	(20) (200)	N.A. N.A.
1.3 Cryogenic flammable or oxidizing		N.A.	45	N.A.	N.A.	45	N.A.	N.A.	10
2.1 Explosives		1[10,13]	(1)[10,13]	N.A.	1/4[12]	(1/4)[12]	N.A.	1/4[12]	(1/4)[12]
3.1 Flammable Solid		125[6,10]	N.A.	N.A.	[14]	N.A.	N.A.	[14]	N.A.
3.2 Flammable Gas (gaseous) (liquefied)		N.A. N.A.	N.A. 15[6,10]	750[6,10] N.A.	N.A. N.A.	N.A. 15[6,10]	750[6,10] N.A.	N.A. N.A.	N.A. N.A.
3.3 Flammable Liquid[4,5,6,7,8,9]	I-A	N.A.	30[10]	N.A.	N.A.	30	N.A.	N.A.	10
	I-B	N.A.	60[10]	N.A.	N.A.	60	N.A.	N.A.	15
	I-C	N.A.	90[10]	N.A.	N.A.	90	N.A.	N.A.	20
	Combination I-A, I-B, I-C[15]	N.A.	120[10]	N.A.	N.A.	120	N.A.	N.A.	30
4.1 Organic peroxide unclassified detonatable		1[10,12]	(1)[10,12]	N.A.	1/4[12]	(1/4)[12]	N.A.	1/4[12]	(1/4)[12]
4.2 Organic peroxide	I	5[6,10]	(5)[6,10]	N.A.	1[6]	(1)[6]	N.A.	1[6]	(1)[6]
	II	50[6,10]	(50)[6,10]	N.A.	50[6]	(50)[6]	N.A.	10[6]	(10)[6]
	III	125[6,10]	(125)[6,10]	N.A.	125[6]	(125)[6]	N.A.	25[6]	(25)[6]
	IV	500[6,10]	(500)[6,10]	N.A.	500[6]	(500)[6]	N.A.	100[6]	(100)[6]
	V	N.L.	N.L.	N.A.	N.L.	N.L.	N.A.	N.L.	N.L.
4.3 Oxidizer	4	1[10,12]	(1)[10,12]	N.A.	1/4[12]	(1/4)[12]	N.A.	1/4[12]	(1/4)[12]
	3[16]	10[6,10]	(10)[6,10]	N.A.	2[6]	(2)[6]	N.A.	2[6]	(2)[6]
	2	250[6,10]	(250)[6,10]	N.A.	250[6]	(250)[6]	N.A.	50[6]	(50)[6]
	1	4,000[6,10]	(4,000)[6,10]	N.A.	4,000[6]	(4,000)[6]	N.A.	1,000[6]	(1,000)[6]
4.4 Oxidizer-gas (gaseous)[6,10] (liquefied)[6,10]		N.A. N.A.	N.A. 15	1,500 N.A.	N.A. N.A.	N.A. 15	1500 N.A.	N.A. N.A.	N.A. N.A.
5.1 Pyrophoric		4[10,12]	(4)[10,12]	50[10,12]	1[12]	(1)12	10[10,12]	0	0
6.1 Unstable (reactive)	4	1[10,12]	(1)[10,12]	10[10,12]	1/4[12]	(1/4)[12]	2[10,12]	1/4[12]	(1/4)[12]
	3	5[6,10]	(5)[6,10]	50[6,10]	1[6]	(1)[6]	10[6,10]	1[6]	(1)[6]
	2	50[6,10]	(50)[6,10]	250[6,10]	50[6]	(50)[6]	250[6,10]	10[6]	(10)[6]
	1	N.L.	N.L.	750[6,10]	N.L.	N.L.	N.L.	N.L.	N.L.
7.1 Water reactive	3	5[6,10]	(5)[6,10]	N.A.	5[6]	(5)[6]	N.A.	1[6]	(1)[6]
	2	50[6,10]	(50)[6,10]	N.A.	50[6]	(50)[6]	N.A.	10[6]	(10)[6]
	1	125[10,11]	(125)[10,11]	N.A.	125[11]	(125)[11]	N.A.	25[11]	(25)[11]

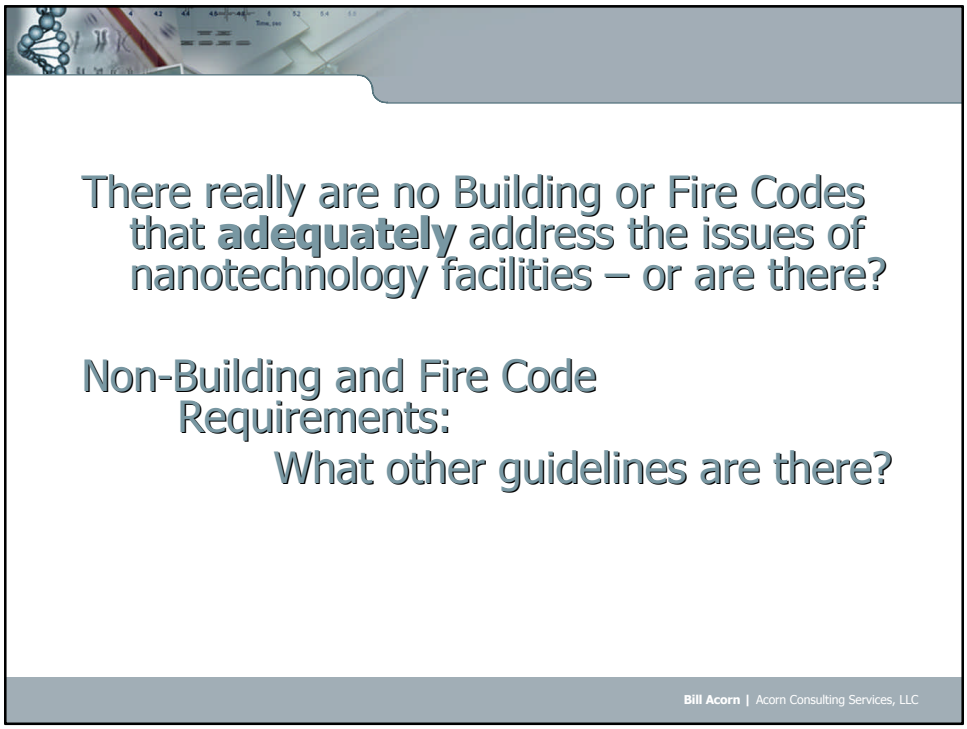
Health Hazards

TABLE 3-E - EXEMPT AMOUNTS OF HAZARDOUS MATERIALS PRESENTING A HEALTH HAZARD MAXIMUM QUANTITIES PER CONTROL AREA[1,2]
When two units are given, values within parentheses are in pounds(lbs.)

MATERIAL	STORAGE[3]			USE[3] - CLOSED SYSTEMS			USE[3] - OPEN SYSTEMS	
	Solid Lbs.[4,5,6]	Liquid Gallons[4,5,6] (Lbs.)	Gas Cu. Ft.[5]	Solid Lbs.[4,5]	Liquid Gallons[4,5] (Lbs.)	Gas Cu. Ft.[5]	Solid Lbs.[4,5,]	Liquid Gallons[4,5] (Lbs.)
	x 0.4536 for kg	x 3.785 for L x 0.4536 for kg	x 0.028 for m^3	x 0.4536 for kg	x 3.785 for L x 0.4536 for kg	x 0.028 for m^3	x 0.4536 for kg	x 3.785 for L x 0.4536 for kg
1. Corrosives	5,000	500	810[6]	5,000	500	810[6]	1,000	100
2. Highly toxics[7]	1	(1)	20[8]	1	(1)	20[8]	1/4	(1/4)
3. Irritants[9]	5,000	500	810[6]	5,000	500	810[6]	1,000	100
4. Sensitizers[9]	5,000	500	810[6]	5,000	500	810[6]	1,000	100
5. Other health hazards[9]	5,000	500	810[6]	5,000	500	810[6]	1,000	100
6. Toxics[7]	500	(500)	810[6]	500	(500)	810[8]	125	(125)

[1]Control areas shall be separated from each other by not less than a one-hour fire-resistive occupancy separation. The number of control areas within a building used for retail or wholesale sales shall not exceed two. The number of control areas in buildings with other uses shall not exceed four. See Section 204.
[2]The quantities of medicines, foodstuffs and cosmetics, containing not more than 50 percent by volume of water-miscible liquids and with the remainder of the solutions not being flammable, in retail sales uses are unlimited when packaged in individual containers not exceeding 4 liters.
[3]The aggregate quantity in use and storage shall not exceed the quantity listed for storage.
[4]The aggregate quantity of nonflammable solid and nonflammable or noncombustible liquid health hazard materials within a single control. area of Group M Occupancies used for retail sales may exceed the exempt amounts when such areas are in compliance with the Fire Code.
[5]Quantities may be increased 100 percent in sprinklered buildings. When Footnote 6 also applies, the increase for both footnotes may be applied.
[6]Quantities may be increased 100 percent when stored in approved storage cabinets, gas cabinets or exhausted enclosures as specified in the Fire Code. When Footnote 5 also applies, the increase for both footnotes may be applied.
[7]For special provisions, see the Fire Code
[8]Permitted only when stored in approved exhausted gas cabinets, exhausted enclosures or fume hoods.
[9]Irritants, sensitizers and other health hazards do not include commonly used building materials and consumer products which are not otherwise regulated by this code.

Table 2.2 **UBC EXEMPT AMOUNTS OF HEALTH HAZARD MATERIAL (UBC Table 3-E) (Note: This table previously Table 9-B)**



Special Biological Hazard Standards and Regulations:

Regulations govern the use, handling, and transfer of certain biologically hazardous bacteria, viruses, toxins, and nucleic acids. In the case of the Center for Disease Control (CDC) regulations (42 CFR Part 73), these agents are referred to as **"select agents".**

The Animal and Plant Health Inspection Service (APHIS) regulations apply to agents or toxins deemed a severe threat to plant health and plant products (7 CFR Part 331) and agents or toxins that pose a severe threat to animal health or animal products (9 CFR Part 121). The specific substances determined by the agencies to be hazardous to humans, animals and/or plants are set forth in lists contained in the regulations. 42 CFR § 73.4, 7 CFR § 331.3, and 9 CFR § 121.3. A good summary of all of the lists is available online from the CDC.

The physical and facility containment criteria for select agents and toxins are defined the CDC/NIH Manual titled, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition.

Special Biological Hazard Standards and Regulations:

Codes and other applicable regulations includes:

- 42 Code of Federal Regulations Part 73 titled "Possession, Use, and Transfer of Select Agents and Toxins: Interim Final Rule"
- 7 Code of Federal Regulation Part 331 and 9 Code of Federal Regulations Part 121 titled: "Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Biological Agents and Toxins"
- CDC NIH Manual titled: "Biosafety in Microbiological and Biomedical Laboratories. 4th Edition"

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Once you know what needs to be done, you must assess the challenges in your facilities

Biosafety Hazard Level – Facility Audits

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed	BSL-1 plus: • Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: Controlled access Decontamination of all waste Decontamination of lab clothing before laundering Baseline serum	Primary barriers = Class I or II BCSs or other physical containment devices used for all open manipulations of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhausted air not recirculated • Negative airflow into laboratory

Biosafety Hazard Level – Facility Audits

The first job is to understand what we are up against.

BUILDING NAME	LIFE SCIENCES	LIFE SCIENCES	LIFE SCIENCES	CANCER RESEARCH	PSYCHOLOGY	PHYSICAL SCIENCES
LAB OR ROOM NUMBER						
PRINCIPAL RESEARCHER						
BIOSAFETY LEVEL 1						
Compliance Issue:						
Lab Has Doors						
Lab Contains Sink for handwashing						
Bench Tops Impervious/Resistant						

Color Key: Green – full compliance with requirement
Yellow – partial compliance
Red – non-compliant with requirement

Biosafety Hazard Level – Facility Audits

BUILDING NAME	LIFE SCIENCES	LIFE SCIENCES	LIFE SCIENCES	CANCER RESEARCH	PSYCHOLOGY	PHYSICAL SCIENCES
LAB OR ROOM NUMBER						
PRINCIPAL RESEARCHER						
BIOSAFETY LEVEL 2						
Compliance Issue						
BSL1 Plus the following:						
Method of Secure Access/Monitoring Controls						
Physical Containment Device or BSC (1,2)						
Class I or II BSC (1,2)						
Adequate Illumination						
Eyewash Station Available						
Biosafety SOP for Lab						
Documented Biosafety Training						
COST OF RETROFIT TO COMPLY	MODERATE	MODERATE	MODERATE	MODERATE	HIGH	LOW

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Biosafety Hazard Level – Facility Audits

BUILDING NAME	LIFE SCIENCES	LIFE SCIENCES	LIFE SCIENCES	CANCER RESEARCH	PSYCHOLOGY	PHYSICAL SCIENCES
LAB OR ROOM NUMBER	[redacted]					
PRINCIPAL RESEARCHER	[redacted]					
BIOSAFETY LEVEL 3						
Compliance Issue						
BSL 2 Plus the following:						
Facility Design and Operational Procedures Documented, Tested, Annual verification						
Passage through a series of two self closing doors						
Physical Security Walls and Ceiling (2)						
Room Surface Impervious/Washable						
Class II Type B2 Biosafety Cabinet (1)						
Biosafety Cabinet Ducted to outside						
Once Through Air Supply						
Room Pressure Controlled Negative						
Existing HVAC Capacity is adequate						
HVAC reliability is adequate						
Outside Air Intake is not contaminated						
Pressure and Airflow alarms						
Autoclave Available(2)						
Vacuum Lines are HEPA filtered						
Hands Free Sink near door						
COST TO RETROFIT TO COMPLIANCE	MODERATE	MODERATE	MODERATE	MODERATE	HIGH	MODERATE

Then, we must define what actions to take……

Personnel Protection & Risk Management

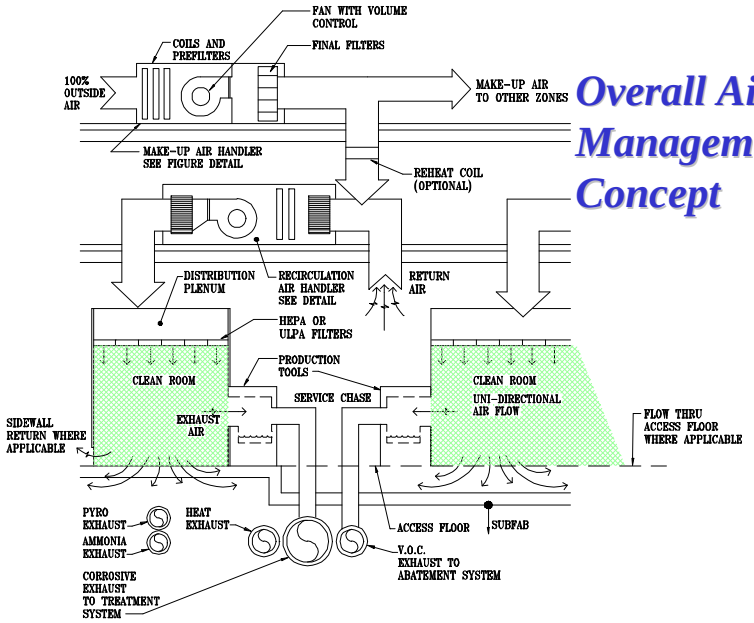
The Issues – Implications on Mechanical and Process System Design:

- Fume Hoods/Fume Hoods in Cleanroom Environments
- Pressure Hierarchy Control
- Open Wet Benches
- Biosafety Cabinets
- Owner's Liability for Employee Health
- H-Occupancy Implications

Personnel Protection & Risk Management

- Fume Hoods/Fume Hoods in Cleanroom Environments
  - Effective capture of challenge materials
  - Energy efficiency
  - Air pattern interruption (in cleanrooms)
  - Noise and vibration
  - Work accessibility/ergonomics
  - Potential exhaust recirculation
  - Maintenance
  - Periodic testing
  - Record keeping

Overall Air Management Concept



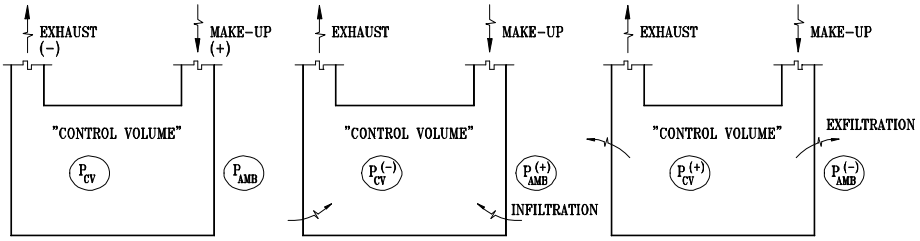
CLEANROOM AIR FLOW SCHEMATIC
NO SCALE

Personnel Protection & Risk Management

- Pressure Hierarchy Control
  - Effective isolation of potential fugitives
  - Effective contamination control
  - Adequate pressure differential without creating safety concerns
  - Cleanroom requirements vs. hazardous lab isolation
  - Operation during smoke or chemical spill events – may need to be different than during normal operation to contain the hazard in the affected zone
  - Pressure hierarchy strategies need to be carefully considered in all operational scenarios and minienvironments may need to be considered to contain the hazards under all scenarios – such as a biohazard hood or other means

MASS BALANCE OR CONTINUITY (SUMMATION OF MASSES = 0)

Most Fundamental Principals



NEUTRAL PRESSURE

AIR BALANCE CONCEPT:

EXHAUST = MAKE-UP AIR

$P_{CV} = P_{AMB}$

"NEGATIVE" PRESSURE

EXHAUST > MAKE-UP AIR

$P_{CV} < P_{AMB}$

NEGATIVE PRESSURE @ CONTROL VOLUME = INFILTRATION FROM AMBIENT ENVIRONMENT

DESIRABLE IN LABORATORY OR OTHER "HAZARDOUS" ENVIRONMENT

"POSITIVE" PRESSURE

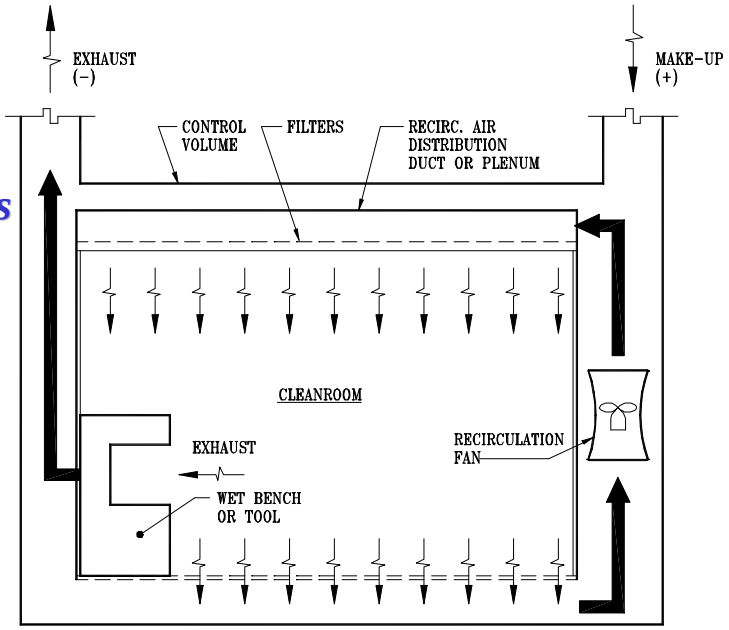
EXHAUST < MAKE-UP AIR

$P_{CV} > P_{AMB}$

POSITIVE PRESSURE @ CONTROL VOLUME = EXFILTRATION TO AMBIENT ENVIRONMENT

DESIRABLE IN CLEANROOM ENVIRONMENT

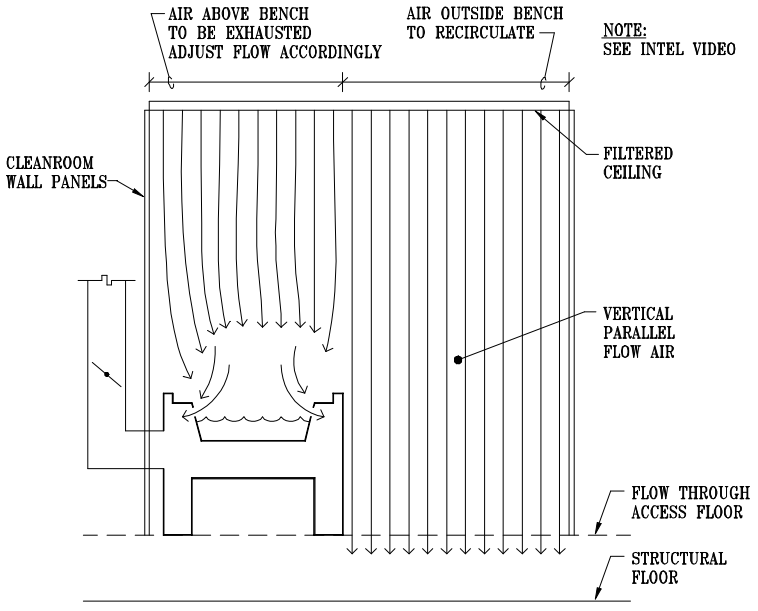
Building on the Principals



CLEANROOM WITHIN BUILDING CONTROL VOLUME

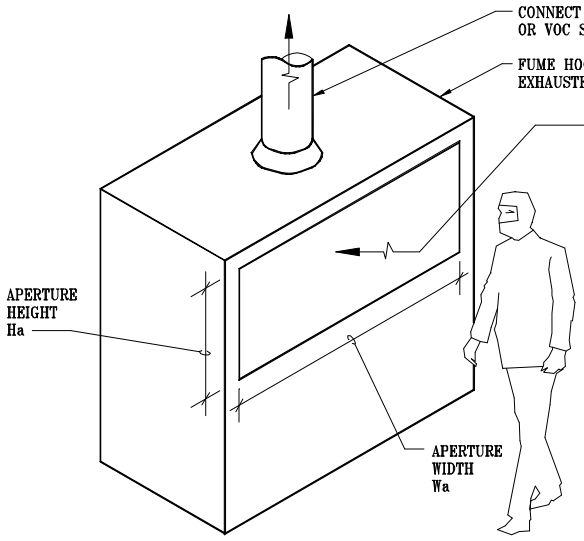
Personnel Protection & Risk Management

- Open Wet Benches
  - Highly accessible working environment
  - Challenging fume capture environment
  - Air pattern interruption via personnel
  - Critical air balance
  - Potential physical contact with hazards
  - Potential liabilities



WET BENCH IN CLEANROOM
FLOW DYNAMICS

CAPTURE AND CONTAINMENT

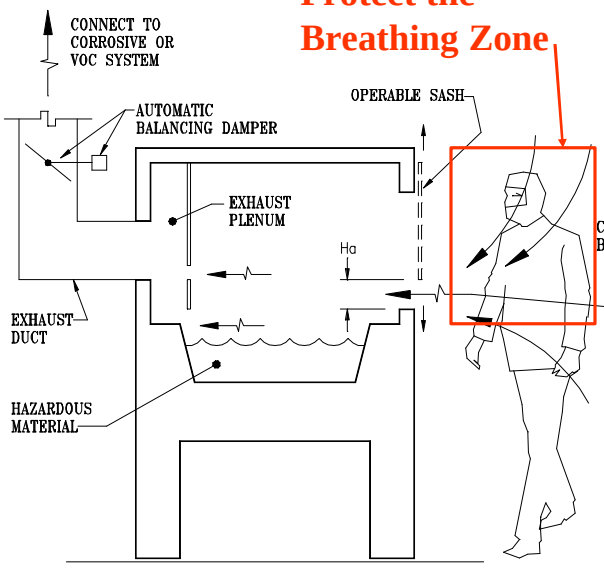


REQUIRED EXHAUST FLOW = Q
Q = Va X Aa
WHERE:
Va = 50–200 FT/MIN
GENERALLY 100 FT/MIN
Aa = Ha X Wa = __FT^2

EXAMPLE:
Wa = 6 FT, Ha = 2 FT
Aa = 12 SQ. FT
Va = 100 FT/MIN
Q = 12 X 100
= 1,200 CFM

HOOD EXHAUST OPTIMIZATION

Protect the Breathing Zone



OPERABLE SASH HEIGHT Ha ALLOWS REDUCTION IN APERTURE AREA Aa WITH CONSTANT APERTURE VELOCITY, RESULTS IN LOWER EXHAUST FLOW Qa.

EXAMPLE:
Wa = 6 FT, Ha = 0.5 FT
Aa = 3 SQ. FT
$Q_{REQ'D}$ = 3 X 100
= 300 CFM

Biosafety Cabinets

BSCs are classified as Class I, Class II or Class III cabinets.

- These are used to effectively contain and capture microbial contaminants and infectious agents using HEPA (High Efficiency Particulate Air) Filters.
- Biosafety cabinets should not be confused with clean benches which only protect the material being worked with and are not suitable for work with infectious or toxic material.

Biosafety Cabinets

Class I BSCs provide personnel and environmental protection, but no product protection. Many of these cabinets have been replaced by Class II cabinets.

Biosafety Cabinets

Class II BSCs are the most commonly used BSC. These cabinets provide personnel, environmental and product protection.

- BSC II safety cabinets are available in several types depending upon the risk associated with the research, as follows (NSF 49 2001)
- Classification depends upn whether the exhaust is discharged outside or can be recirculated to the building
- Contaminant exhaust ducts should always be at negative pressure inside the building.

Biosafety Cabinets

Class III BSCs are fully enclosed cabinets of gas tight construction in which access to the research materials is only obtained via **gloves** attached to the front of the cabinet. The cabinets are maintained under negative pressure. Class III cabinets are generally reserved for use with high risk biological agents, frequently in BSL 4 laboratories.

Biosafety Cabinets

So…. When do you use each type?

- As mandated by regulations
- As mandated by corporate or institutional policy
- As determined by a **risk analysis**

Personnel Protection & Risk Management

- Owner's Liability for Employee Health
  - What is the employer's obligation?
  - How much exposure is acceptable?
  - What is the acceptable standard of care?
  - Written policies
  - Atmosphere of inquiry
  - What is the burden of proof?
  - Is there a statute of limitations?
  - Lessons from the Semiconductor Industry?

Personnel Protection & Risk Management

- Hazardous Materials
  - Chemicals – liquids, gases and solids
  - Biohazards
  - Employee education
  - Emergency response teams
  - Continuous assessment of the risks
  - Record keeping
  - Regulatory agency liaison

Personnel Protection & Risk Management

- H-Occupancy Implications
  - What kind of occupancy is this?
  - What Building and Fire Code rules apply?
  - If looks like a hazardous occupancy … is it?
  - What is the pro-active strategy to pursue?
  - Working with the local regulators

Interpretation of Codes and Standards:

The applications and interaction of various codes relating to special risk occupancies are complex, to say the least. Proper interpretation of government codes, company directives and other standards goes beyond a general understanding of the words used in those documents. An **under-standing of the context in which the standards are intended and the spirit and intent of the regulations is required**.

Interpretation of Codes and Standards:

Our actions must be forward thinking/pro-active in considering all potential risks and attempting to mitigate them, yet at the same time, there is a job to be done.

How do we balance these seemingly contradictory goals?

Interpretation of Codes and Standards:

Beyond legal requirements, an owner's corporate safety policies and insurance carrier requirements may dictate additional risk mitigations. These guidelines go beyond minimum design and construction standards to ensure **good engineering practices** are employed. Such practices address the many safety, health and other issues that pertain to any hazardous occupancy facility including exhaust systems, pressure hierarchies, security systems, biohazard containment, exit corridors, life safety alarm systems, fire suppression, chemical delivery routes, chemical storage, etc.