
2017 CSHP Ontario Branch 69th Annual Conference
Annual General Meeting and Educational Sessions

***Workshop D -
Planning and Design of Sterile Compounding Facilities:
Case Studies Review***

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18 November 2017

Presenter Disclosure

- Presenter's Name: **Steve Black**
- I have no current or past relationships with commercial entities.
- Speaking Fees for current program:
 - I have received a speaker's fee from **CSHP-Ontario Branch** for this learning activity.

Commercial Support Disclosure

- This program has received no financial or in-kind support from any commercial or other organization.

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Introduction



Steve Black

Architect and Healthcare Planner
Project Manager, University Health Network

Note: the opinions expressed are not intended to reflect the perspectives of University Health Network's Pharmacy Department.



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Objectives

- 1) To develop a better understanding of the larger role of the physical environment in compliance with compounding standards and guidelines and achieving desired outcomes.
- 2) To see how standards may be applied to site-specific situations in sterile compounding facilities.
- 3) To explore a range of considerations for entering into the planning and design of the physical environment.



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Workshop

Format:

- 15** minutes – introduction and presentation (context)
- 50** minutes – review of case studies
- 10** minutes – summary comments, questions, wrap-up

Follow-up:

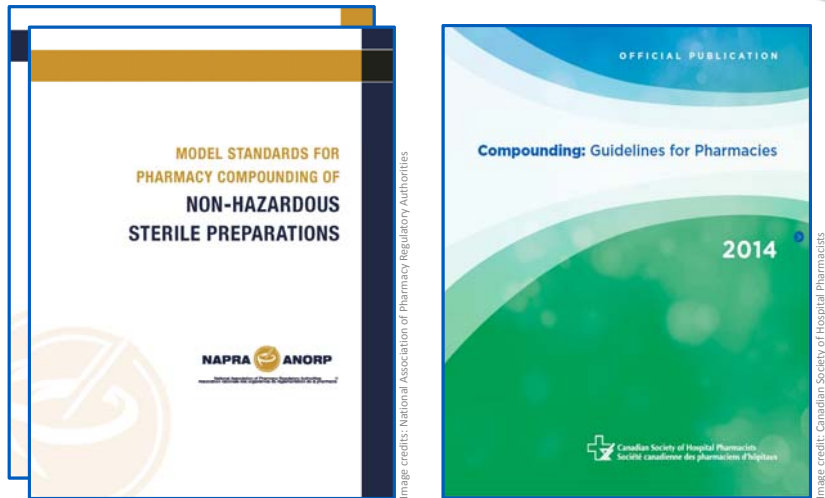
Case study drawings and summary of discussion will be compiled and distributed to workshop participants and contributing organizations.



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Reference



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Context

Looming compliance deadlines.

Pending construction/renovation activity:

-significant cost, disruption, risk, ...and grief.

Need to get it right:

-hard compliance

-future proofing

-creating a space that supports efficient effective operations while enhancing desired outcomes

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Desired Outcomes

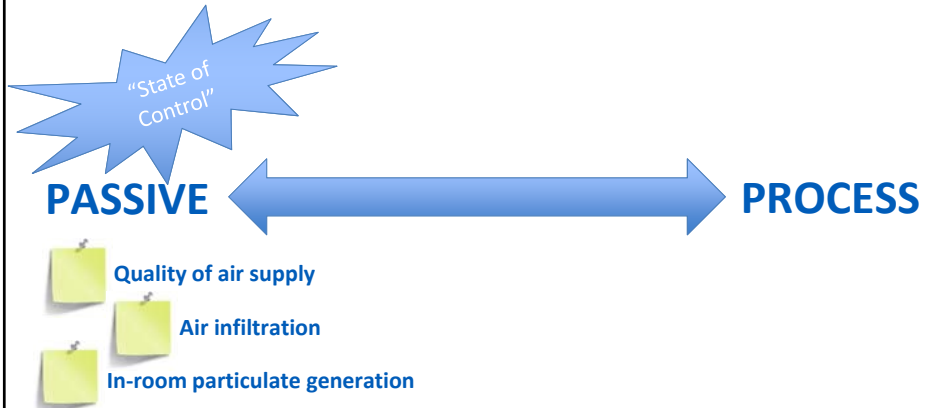
The safety of the patients and pharmacy personnel is central to compounding standards and guidelines

- Protection of the **Preparation**
e.g., contamination, accuracy, error
- Protection of **Personnel**
e.g., exposure to hazardous substances

Role of the Physical Environment

PASSIVE  **PROCESS**

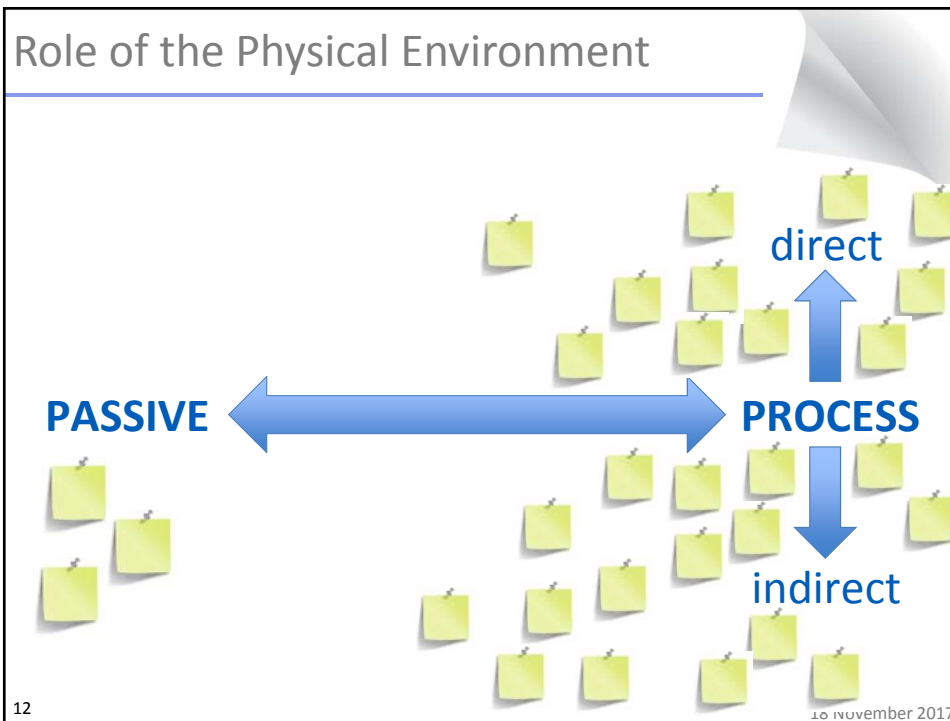
Role of the Physical Environment



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Role of the Physical Environment



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Role of the Physical Environment

Passive Influences:

- Creating a “state of control”
- Passively reducing and preventing opportunity for contamination of the physical environment
- Focus on three primary sources:
 - 1) quality of air supply (HEPA filtration; air exchange rate)
 - 2) limiting opportunities for air infiltration
 - 3) minimizing the in-room generation of particulate (equipment, finishes)

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Role of the Physical Environment

Process Influences:

- Shaping the physical environment to support the process of compounding and the actions of personnel
 - Reduce opportunity for contamination, inaccuracy, and error
 - Support the comfort and safety of compounding personnel
 - Minimizing activity detrimental to maintaining good air quality
 - e.g., opening/closing doors

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Role of the Physical Environment

Process Influences:

- Examples:
 - e.g., creating logical, intuitive workflow
 - e.g., building materials that support effective cleaning and disinfection
 - e.g., reducing ambient stress (heat, noise, ergonomic considerations)
 - e.g., reducing distraction and diverted attention

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Role of the Physical Environment

Process Influences:

- Examples:

- DIRECT** → e.g., creating logical, intuitive workflow
 - e.g., building materials that support effective cleaning and disinfection
- INDIRECT** → e.g., reducing ambient stress (heat, noise, ergonomic considerations)
 - e.g., reducing distraction and diverted attention

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Influence on Process

- **Tools** are made available and correctly located
- Proper **Flow** is accommodated
- **Space** is designed to support specific activity

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Influence on Process

Tools:

- For example:
 - sinks / ABHR
 - sharps containers
 - waste receptacles
 - hands-free intercom
 - line of demarcation
 - ceiling HEPA filters that are easy to replace

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Influence on Process

Flow:

- For example:
 - logical circulation (e.g., reducing unnecessary movement)
 - use of pass-through chambers
 - space for queuing in staging area
 - efficient progression of activities
 - appropriate storage of supplies (quantity, location)

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Influence on Process

Space:

- For example:
 - adequate area for tasks
 - appropriate configuration
 - clutter-free
 - flexibility
 - room to clean properly
 - separation of circulation space from workspace

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Reality Check

“It is commonly understood that most contamination is related to the actions of compounding personnel compared to other sources.”

(CSHP Compounding: Guidelines for Pharmacies (2014))

Reality Check

“The most important variable affecting microbial contamination of admixtures was the aseptic technique of personnel, not the environment in which the drugs were compounded.”

(Thomas M., Sanborn M., Couldry R. I.V. admixture contamination rates: Traditional practice site versus a class 1000 cleanroom Am J Health Syst Pharm. 2005; 62:2386-92)

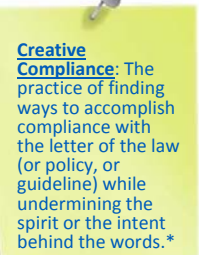
Question:

When presented with a “rule”, do you...

A) Endeavour to satisfy the underlying principle?

B) Plant your toes on the line and lean as far forward as you can?

*McBarnet DJ. *When compliance is not the solution but the problem: from changes in law to changes in attitude.* Canberra (AU): Australian National University, Research School of Social Sciences, Centre for Tax System Integrity; 2001 [cited 2014 Jun 24]. Available from: <http://asiapacific02.cap.anu.edu.au/sites/default/files/CTS1-WorkingPaper18-full.pdf>



Creative Compliance: The practice of finding ways to accomplish compliance with the letter of the law (or policy, or guideline) while undermining the spirit or the intent behind the words.*

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Why Does it Matter?

Risk of...

...contaminated preparations

...staff exposure to hazardous substances

...medication error (slips and mistakes)



New England Compounding Center Meningitis Outbreak (Sept 2012):
...800+ sickened
...76 deaths

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The Construction/Renovation Project

The capital planning process:

- Construction Cost \neq Project Cost
- Include reserve/contingency funds
- Feasibility studies to inform budget \rightarrow scope and resultant infrastructure upgrades
- Allow time for:
 - Feasibility studies and scope definition
 - Detailed user engagement
 - Funding approvals
 - MoHLTC/LHIN approvals (i.e., 6-8 week turnaround + questions)
 - BPS rules for procurement (consultants, contractors)
 - Unforeseeable conditions

Note:
MoHLTC project approvals required regardless of funding source.

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The Construction/Renovation Project

Other considerations:

- **Engage** and **educate** the whole team
- The **quotidian disconnect**
- Foundational microbiology
- Beware of the lure of past project success
- Avoid (...unnecessary...) complexity
- Plan process and environment in tandem
- **Absence of evidence** \neq evidence of absence
- Design processes for '**prevention**' and for '**containment**'
- Incorporate '**future proofing**' wherever feasible
- Watch for perfection paralysis...just do it!

Quotidian:
a class of activities deemed commonplace, ordinary, trivial, or mundane.

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Final Thought

“The most damaging phrase in the language is
‘we’ve always done it this way!’”

(Rear Admiral Grace Murray Hopper, March 1987)