

Overview of PPE Choice, Use, and Recommended Practices



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Overview of PPE Choice, Use and Recommended Practices

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Disclosures

I do not have any relevant financial disclosures for this presentation and attest that recommendations are evidence-based and free of commercial bias.

(E.G., Peer-reviewed literature, adhering to evidence-based practice guidelines)

Objectives

- **Understand:**
 - PPE within the matrix of safety controls
 - Linking PPE selection / donning and doffing to the context provided by these controls
- **Identify**
 - Most common PPE components and understand the intention and proper use of each one
 - Importance of high-quality SOPs in environments supporting high levels of isolation
- **Implement**
 - Awareness of Administrative Controls as the bridge ensuring staff understand how to utilize existing safety controls effectively
 - Considerations for both creating and updating SOPs, including potential downstream impacts

Transmission Based Precautions

Standard and Transmission-Based Precautions

Standard Precautions: A set of infection prevention and control practices to prevent the exposure to bodily fluid and halt spread of pathogens.

Transmission-Based Precautions: Specific controls, processes, and PPE components used in addition to standard precautions when certain symptomatology of infections are present.

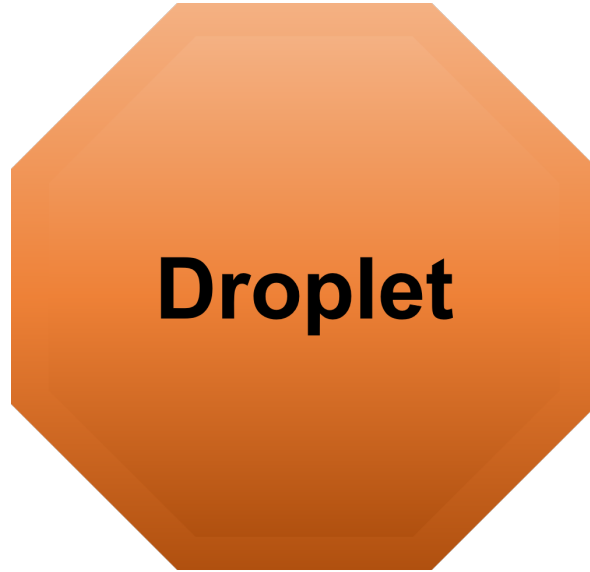
Dress for Transmission



Contact



**Gloves, eye
protection,
gown/apron**



Droplet



**Gloves, eye
protection,
apron/gown,
mask**



Airborne



**Gloves, eye
protection
gown/apron,
respirator**

H5N1
Minimum
PPE
(clinicians)



Transmission Mode

What is Personal Protective Equipment?

PPE is usually clothing and/or equipment that is worn or used in order to provide protection against hazardous substances or environments.

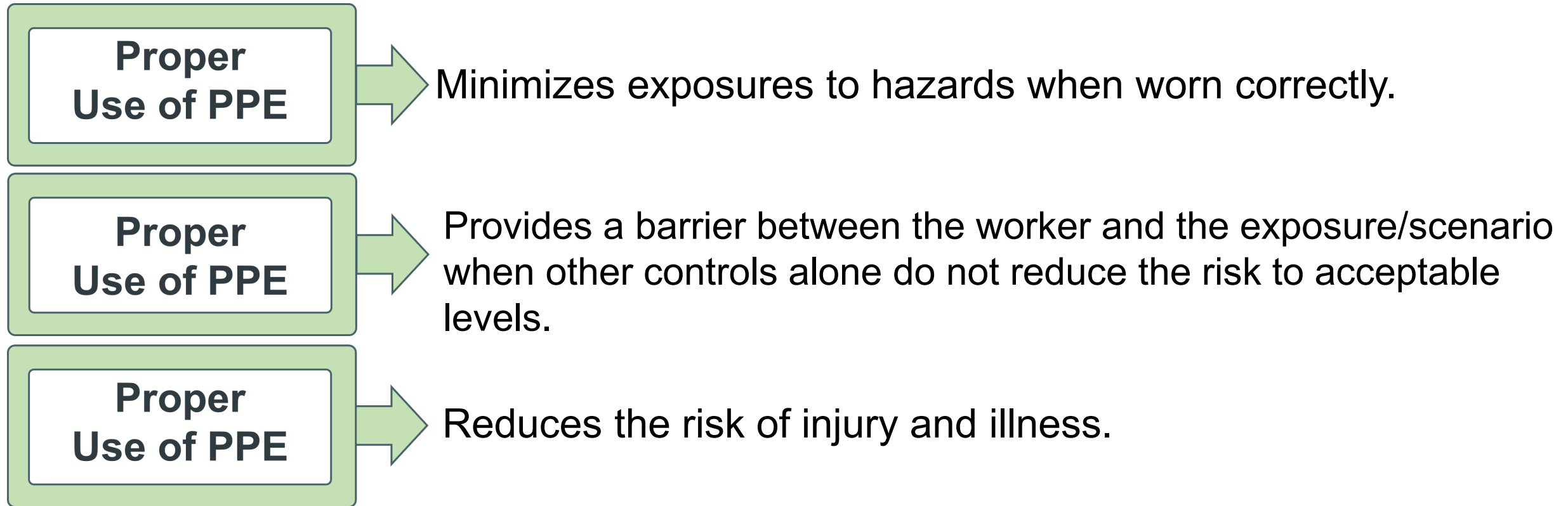
It is a barrier between you and a hazard. This barrier can then act to minimize your exposure to the hazard.

Donning is putting on your PPE.

Doffing is taking off your PPE.



Why Use PPE

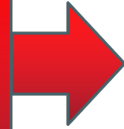


Training, practice, competence, and observation is key to safe and effective use of PPE.

PPE Selection Review

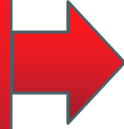
What PPE does NOT do

CAUTION



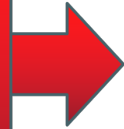
PPE does **not** eliminate the need for additional controls, such as engineering and administrative.

CAUTION



PPE does **not** protect: what it is not covering, when it is not donned correctly, or when it was not selected correctly.

CAUTION



PPE does **not** address the hazard directly but provides layers of protection from the hazard.

The use of PPE does NOT guarantee protection from the hazard. This is especially true if doffing technique is performed incorrectly.

Prior to Donning PPE

Once PPE has been selected ALWAYS:

- Identify a safe area prior to donning:
 - “Safe” can be a subjective word, but your safe donning area is ideally an area located in the clean part of the unit, away from frequent activity, and close to the components you’ll be donning
- Locate the doffing area and familiarize yourself with the space:
 - Does it have the appropriate supplies and waste receptacles and enough space to move easily?
- Inspect all components of PPE.
 - Check for rips, tears, appropriate sizing, fit and manufacturing defects.
- If any components of the PPE are reusable, what is needed for the proper decontamination, care, and maintenance?
- Establish a plan for proper and safe disposal of PPE.
 - Ensure communication of this plan to the team

PPE Selection

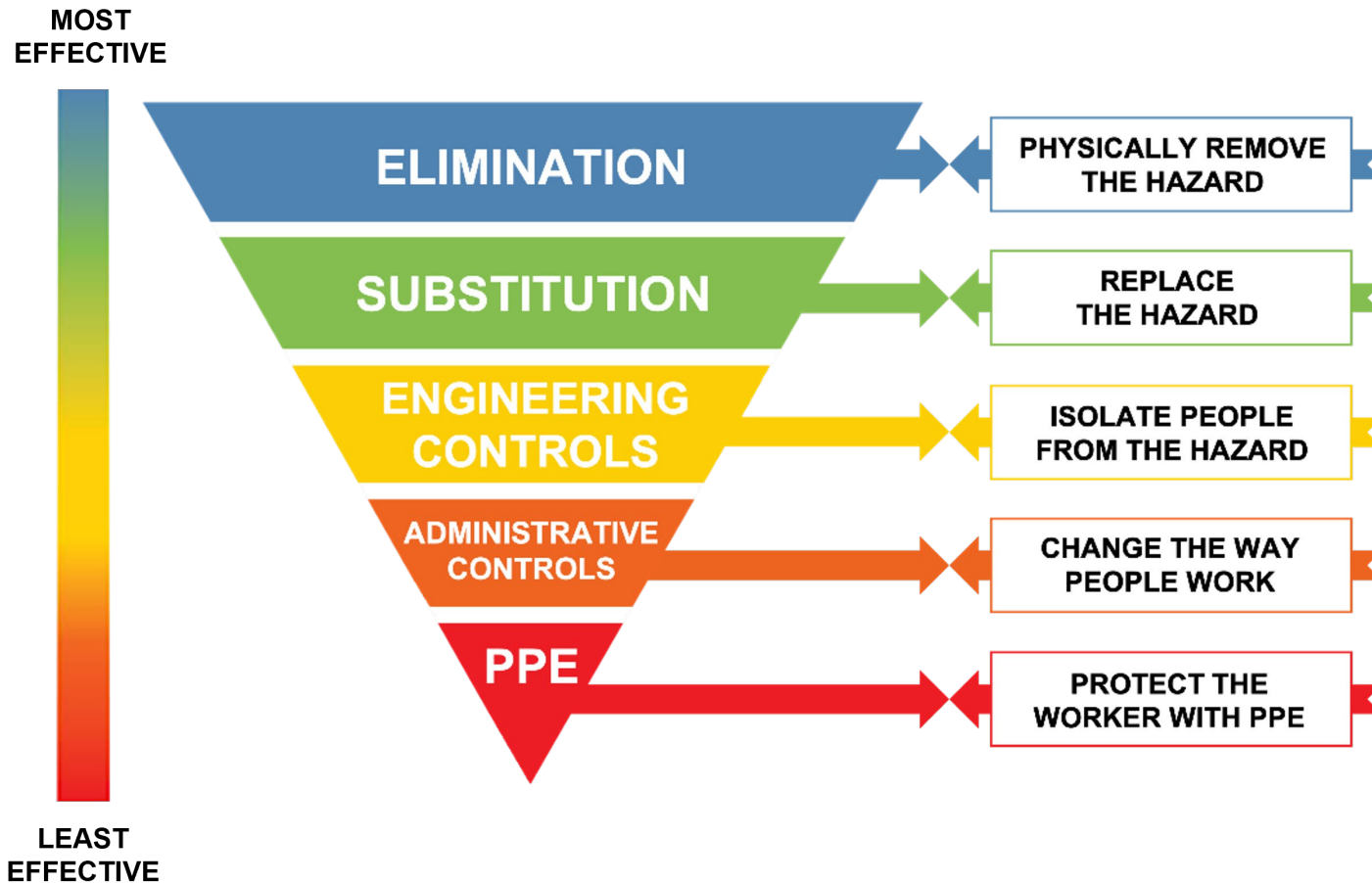
Selection of PPE should be based on:

- CDC recommended standards and transmission-based guidelines
- Risk of exposure to bodily fluids (Leveling up)
- Operating environment
- Expectations should be reviewed and updated regularly to ensure mitigation of any newly identified potential safety issues



Hierarchy of Controls

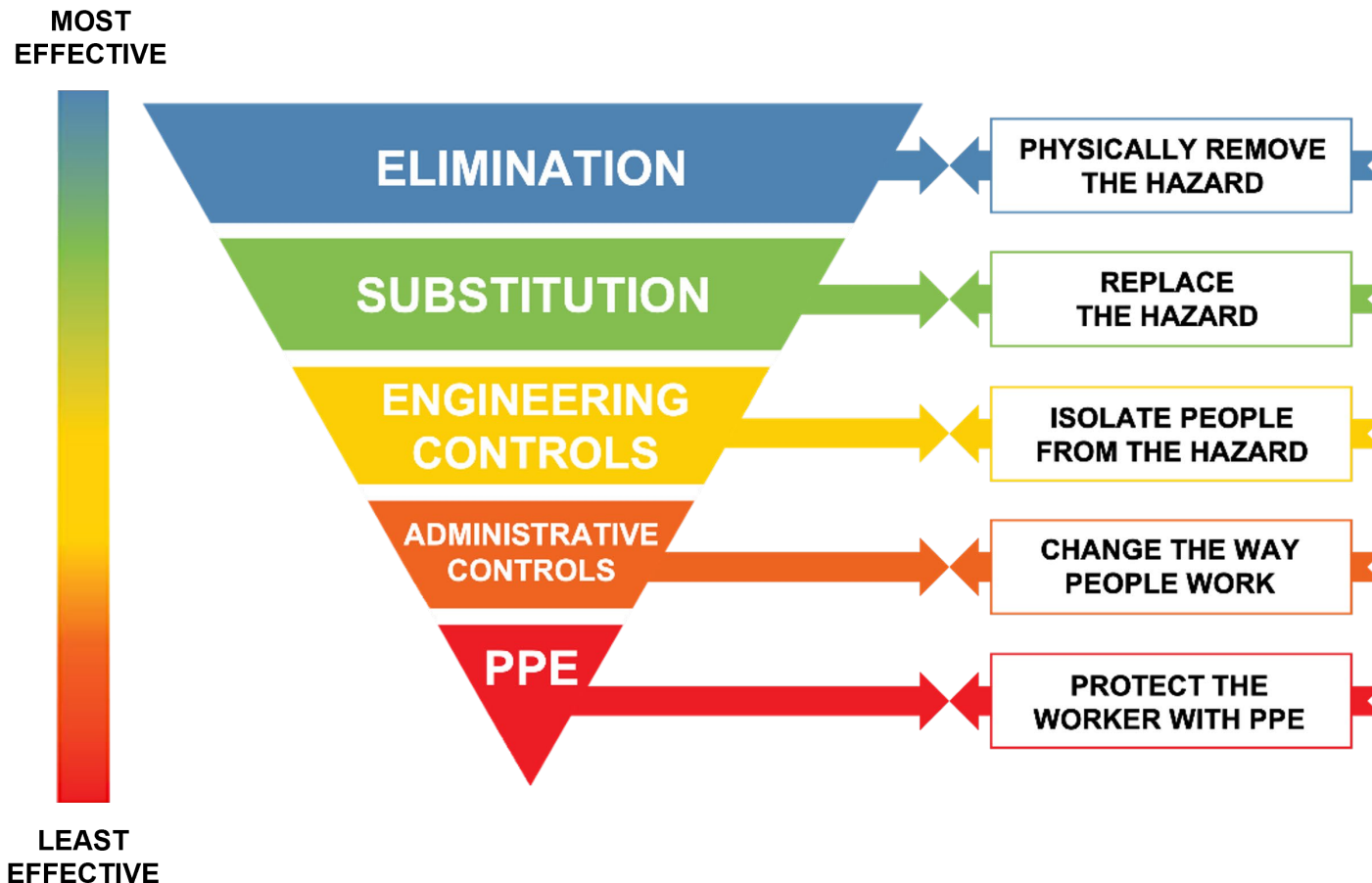
Hierarchy of Controls: An Overview



- The Hierarchy of Controls (HOC) was developed by the National Institute for Occupational Safety and Health (NIOSH).
- The HOC was developed as a tool to reduce injury and illnesses in all workplaces.
- As a Hierarchy, it displays the interventions to consider from the most effective to the least effective when developing plans to avoid occupational injury or illness.

How to use Hierarchy of Controls

Starting at the top, implement each applicable layer before moving to the next.



Recognize the hazard:

- **Can it be removed?**
- **If not, can it be replaced with something safer?**
- **If there is no substitute, can it be avoided?**
- **Implement safer workflows.**
- **Protect workers with PPE.**

Hierarchy of Controls - Practice

Situation

An excess of caustic chemicals are in the storeroom. With the amount of chemicals in the room, compliance is fearful for an event

Identify the Hazard(s)

Excess of Caustic chemicals

MOST
EFFECTIVE

Elimination

Reduce or remove all caustic chemicals from the storeroom to designated safe space.

Substitution

Identify a safer solution that provides the same result as the caustic chemicals

Engineering controls

Utilize specific equipment when pouring and moving caustic chemical (Funnel, Cart)

Administrative controls

SOPs that define how much chemical is to be used for application

PPE

Wear appropriate chemical PPE

LEAST
EFFECTIVE

Hierarchy of Controls – Practice (continued)

Situation

Clinical interaction with inoculated animal models

Identify the Hazard(s)

Risk for exposure to HCID

MOST
EFFECTIVE

Elimination NA

Substitution NA

Engineering controls Isolation, negative pressure room, more

Administrative controls Zoning, Workflows, Policies and Procedures

PPE Identified PPE ensemble

LEAST
EFFECTIVE

Controls and Risk Mitigation

Engineering controls

Environment / architecture, Negative air-flow, restricted access, autoclaves, portable isolation, anterooms, visual aids

Engineering / environmental controls generally are least flexible to modify easily; initial design of isolation units or lab spaces guides how other controls are implemented

Administrative controls

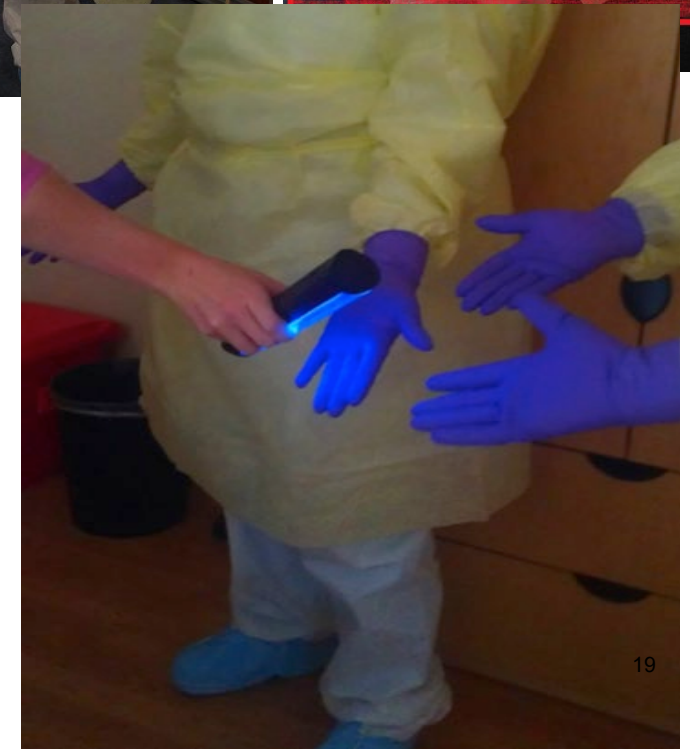
SOPs, staffing grids, staff roles, zones, entry & exit flow, equipment integrity checks

Administrative controls are not passive: SOPs are living documents updated with discernment. Documents track staff equipment use, chain of custody, training via exercises, videos, knowledge checks, engaging practical scenarios, all ensure staff are aware of and use existing controls correctly.

Safety Control

Identified PPE ensemble

Engineering / Environmental Controls, and PPE Safety Controls only work as well as the staff's understanding of how to employ them.



PPE Components

Procedure Masks



- Procedure masks protect against large particle droplets, splashes, sprays, and splatter.
- They are effective as source control by preventing droplets entering the environment.
- Fit testing is not required.
- Procedure masks must be worn correctly.

- **Procedure masks are not respiratory protection!**

Filtering Face Piece Respirator



For reliable protection, individuals must be fitted to a NIOSH-certified N95 model.

- Hair should be securely pulled back away from the face.
- Facial hair that interferes/overlaps the border/ boundary of the respirator may affect its ability to properly seal.
- Always perform a user seal check.
- A new fit test should be conducted when an individual experiences any physical changes that could change the contouring of the face (and thus, the effectiveness of the seal)

FFPs provide respiratory protection!

Powered Air Purifying Respirators (PAPRS)



Should have a disposable head cover with cape/ shroud that extends over the shoulders and fully covers the neck

All components must be compatible with that particular PAPR unit

Can have either integrated helmet/blower motor or belt worn external filter and blower unit

Confirm with the manufacturer what cleaning solvents are compatible with the equipment

Related Administrative Controls to Consider:

PAPR Assignment Tracking Sheet

(ensures same care provider uses same helmet during shift, verifies equipment has been checked for functionality)

Face Shield or Goggles



Use eye protection when individuals show signs of infection and/or when there is a risk for splash.

Face shields protect the eyes, face, and front of neck against respiratory droplets.



Goggles protect the eyes against respiratory droplets but provide minimal protection for the rest of the face.



Gowns/ Coveralls

- Gowns are a barrier to prevent contamination to clothing and skin.
- There are different levels of gowns that range from being low-level barrier protection to fluid impervious.
- Fluid resistant fabrics resist liquid penetration but will allow penetration with time and pressure.
- Fluid impervious fabrics have demonstrated an ability to prevent liquid penetration under test conditions.



Gown Risk Zones



When working in a gown, there are certain areas that are more likely to become contaminated:



Right sleeve



Front



Left sleeve

Helpful Considerations:

Always be particularly aware of risk zones, especially when doffing

Risk zones aren't static: may change based on where you are in relation to the source of contamination

Be familiar with room layout, equipment placement; these can be threats to PPE integrity

Gowns as an Example of Potential PPE Compromise

- Situational awareness and deliberate navigation of the contaminated area ensures that emergent issues with PPE components or inadequate component selection and use (sizing, securing) do not occur due to user actions
- Ensure that training in PPE includes understanding of the areas at higher risk for potential compromise (such as securing the gown closed at the back)

Expert tip:

Ensure you are always facing front-first when at cageside



Gloves

Gloves act as a barrier to prevent contamination to your hands.

Use when:

- Working with animals
- Handling items that are potentially contaminated.

Change when there is visible soil and between tasks.

Considerations:

- Wear three pairs of gloves so the 2nd layer can be considered your skin.
- Wear long cuff gloves to cover the wrist band on your gown.
- Perform hand hygiene on your gloves prior to removing them.



Gloves are not a substitute for hand hygiene.

Head Covers



- Should be impermeable to fluids
- Hoods should fully cover hair, forehead, neck to jaw but should not interfere with fit or function of the N95 respirator
- Some may come too close to eyes on wearer's face – consider wearing safety goggles for comfort and safety
- Considerations should be taken into account regarding increased heat due to less air flow

Disposable boots/ shoe covers

- Single-use (disposable) boot covers that extend to at least mid-calf
- Should have non-skid soles
- Single-use (disposable) shoe covers are acceptable only if they will be used in combination with a coverall with integrated feet.



Role of Safety Observer or Donning and Doffing Partner

- **Safety Observer:** Team member that is responsible for safely guiding a worker in the process of donning/doffing PPE and/or ensuring safe patient care operations.
- **Safety is the priority**
 - Reading out step-by-step instructions
 - Actively observes and assists with donning/doffing process
 - Knowledgeable on how to adapt processes if needed
- **Monitors team members to ensure safe practices**
 - Observes PPE for contamination
 - Observes contamination points during patient care
 - Redirects when unsafe practices/behavior are observed

Possible Failure Points of PPE

- 1. Insufficient training:** Proper training is required on PPE components.
- 2. Improper Donning:** Can reduce PPE's effectiveness, complicate doffing, increase risk of contamination.
- 3. Ill-fitting PPE:** Can increase risk of exposures
- 4. Incorrect PPE:** Incorrect PPE selection reduces protection from hazard, environment.
- 5. Reuse:** Only PPE items that are meant for reuse and can be appropriately decontaminated should be reused.
- 6. Appropriate Disposal:** PPE should be gently placed in an appropriately sized receptacle. Waste container liner should be replaced at 3/4 full.
- 7. Hair and Facial Hair:** Hair should be pulled securely back away from the face. Facial hair can prevent proper seal of respirators.

Escalating to a Higher Level of PPE

- Face shield or goggles
- N95 respirator

- Single use or launderable gown

- Gloves: single or double layer

- Scrubs and no shoe coverings



- Fluid-resistant hood extending to shoulders
- Face shield
- N95 respirator

- Single use gown or coverall that is at a minimum fluid resistant

- Gloves: double layer with extended cuffs as the first layer

- Optional - single use fluid-resistant apron

- Single use fluid-resistant shoe coverings

- Side-by-side comparison of escalating the PPE ensemble

Escalating to a Higher Level of PPE (NIH – Special Clinical Studies Unit)

- **CAPR w/ Face shield**

*Controlled Air Purifying Respirator

- **Single use impervious gown**

- **Gloves: Double Layer**

- **Paper Scrubs, 1 pair ankle-height foot covers**



- **PAPR with filter hood and double shroud**

- **Disposable, fluid resistant coveralls worn under impervious gown**

- **Gloves:**
Double layer with extended cuffs, 1st layer gloves taped to coverall cuffs, second layer cuff placed over outer gown

- **2 disposable foot covers**

• **Side-by-side comparison of escalating the PPE ensemble**

Highlighting Administrative Controls

The Importance of Administrative Controls

Administrative Controls ensure:

- ☐ Historical knowledge maintains itself regardless of staff turn over
- ☐ Consensus understanding of performance expectations when cross-training/onboarding new staff
- ☐ A map exists for every procedure or action, highlighting the path with the safest outcome

Administrative controls empower staff to properly utilize Engineering and safety controls:

- ☐ Through Standards of Practice that have been tested for efficacy prior to an actual event
- ☐ By tracking of performance accountability and templating effective training opportunities
- ☐ Using staffing grids, flow charts and other visual aids to minimize uncertainty through consistency

Your SOPs are a cornerstone of safe practice but only if they are read and followed by staff:

- ☐ Write clearly and concisely, using simple action verbs, avoiding words that are vague (“typically, generally”)
- ☐ Be as brief as possible, using common terminology and active voice
- ☐ Avoid long paragraphs:
 - a. As a general rule, each action needing to be taken should receive its own bulleted or numbered “step” **but**:
 1. Used sparingly, a step can also be broken down further like this
 2. Provides a nested mini-process guide for actions which may not be self-explanatory
 3. Great if clarification is not enough to warrant an additional SOP

Poorly written SOPs tend to result in poorly executed outcomes

Bad procedures can be a recipe for disaster

Bad Procedures

Cause errors and frustration

Lack context or focus on correct audience

Written too narrowly or vaguely to allow staff confidence to navigate issues that may arise

Detract from quality goals

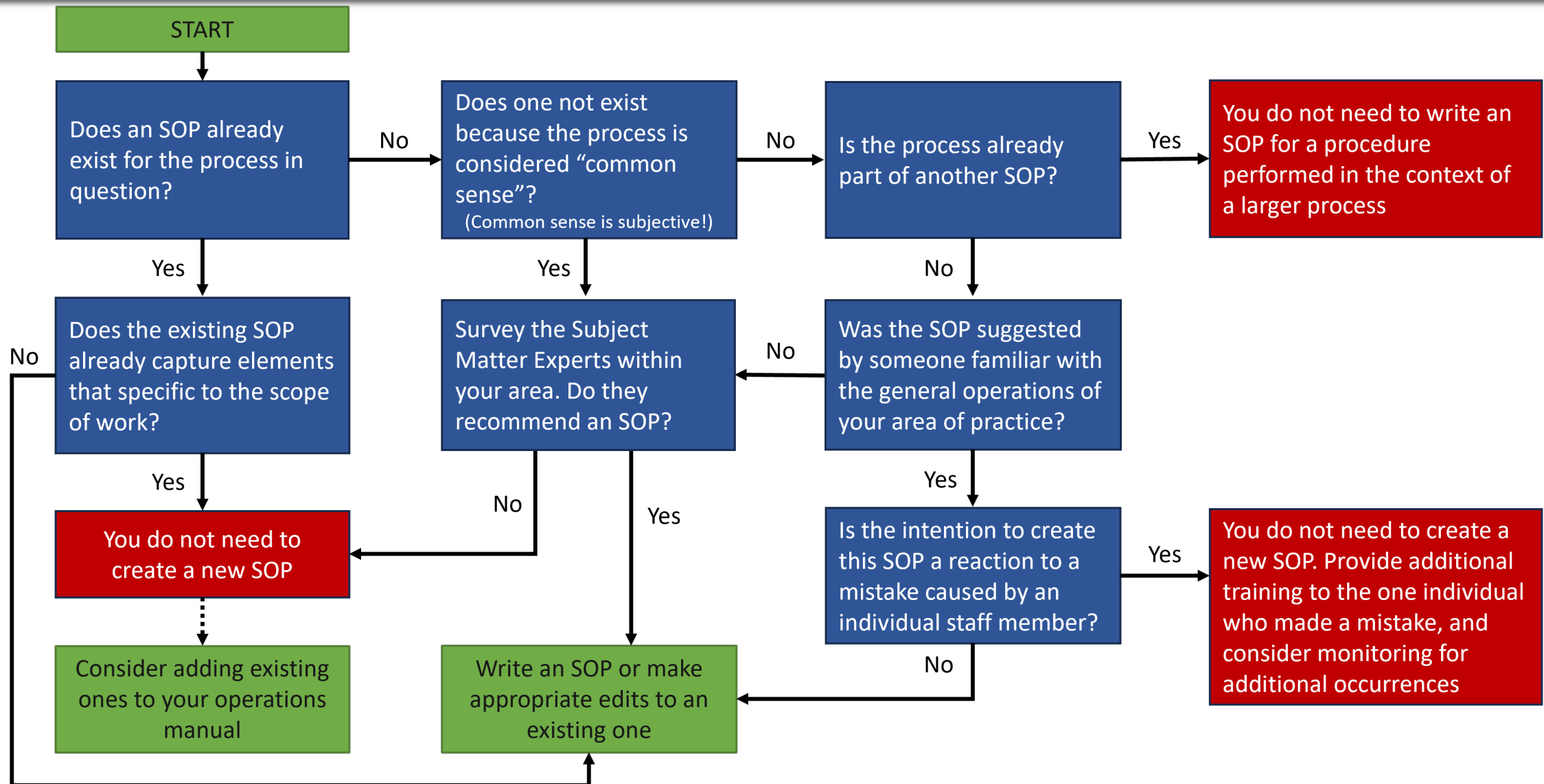
Don't get read or used

Effective Procedures

Effective procedures can be a recipe for success

- Maintain consistency of action amongst staff
- A living document to be modified as needed due to resource changes, equipment or staff feedback
- Should be developed with Subject Matter Expert(s) involvement relevant to the topic
- Backbone for training materials development
- Road tested by both individuals familiar and unfamiliar with the process

Helpful Considerations on when to create an SOP:



Templates are your friend

- Use SOPs that meet standards /expectations of your institution or facility and customize them as needed
- Use templates for SOPs that outline procedures fairly universal in nature and modify as necessary
- Ensure all essential procedures have an SOP, but use discernment: unnecessary SOPs can lead to superfluous performance evaluation

You don't need to re-invent the wheel.

You don't need extra wheels.

Helpful template examples:

<https://www.nidcr.nih.gov/sites/default/files/2017-12/standard-operating-procedure.doc>

<https://www.niaid.nih.gov/research/just-time-sop>

<https://www.niaid.nih.gov/sites/default/files/sops-template.docx>

https://rcra.emory.edu/_includes/document/s/sections/oric/gcpguidesamplesops.docx

SOP S3 Staff Responsibilities, Duties and Job Descriptions

SOP S4 Site Staff Education and Training

SOP S5 New Site Staff Orientation

SOP S6 Site Staff Communication Process

SOP S7 Staff Performance Reviews

SOP S8 Site Staff Meeting

SOP SC1 Study Termination or Close-out Visit

SOP SC2 Test Drug Destruction at Study Site

SOP SC3 Archiving of Study Data

SOP SC4 End-of-Trial Report

SOP T1 Site Initiation Visit

SOP T2 Subject Recruitment to Enrollment

SOP T3 Obtaining Written Informed Consent

SOP T4 Investigational Products Accounting, Dispensing and Administration

SOP T5 Blinding - Codes and Code Breaking

SOP T6 Paper Case Report Form Completion

SOP T7 Remote Data Capture

SOP T8 Data Clarification

SOP T9 Randomization

SOP T10 Monitoring Visit

SOP T11 Preparing and Managing Source Documents

SOP T12 Records Retention

SOP T13 Specimen Collection Handling and Shipping

SOP T14 Continuing Review or Progress Reports and Communications with IRB

SOP T15 Adverse Event and Serious Adverse Event Reporting

SOP T16 Study Interim Data Analyses and Reports

SOP T17 Data and Safety Monitoring Committee

SOP T18 Protocol Deviations and Violations

Appendix - Terminology

SOP P1 Pre-Study Visit

SOP P2 Review of Protocol

SOP P3 Review of Protocol Amendments

SOP P4 Review of Investigator

SOP P5 Review of Case Report Form

SOP P6 Study Organization and Planning

SOP P7 Study Team Definition of Responsibility

SOP P8 Recruitment of Subjects

SOP P9 Pre-Study Planning Investigational Products

SOP P10 Pre-Study Planning Lab Investigations

SOP P11 Investigator's meeting GCP training

SOP 12 Ethics Committee or IRB application and communications

SOP P13 Regulatory Authority Applications and Documents

SOP P14 Vulnerable Subjects

SOP QA1 Study Specific Audit

SOP QA2 Study Specific Inspection

SOP QA3 Preparation, Approval, Review and Maintenance of SOPs

SOP QA4 Human Research Protection Program

SOP QA5 Fraud and Misconduct

SOP QA6 Confidentiality Agreement Obligations and Practices

SOP QA7 Participant's Complaints

SOP QA8 Emergency Resuscitation - Cardiac Arrest

SOP QA9 Trial Registry

SOP QA10 Conflict of Interest Resolution

SOP QA11 Feasibility Study

SOP S1 Description of Organization Structure

SOP S2 Staff CV

Strategies to ensure active engagement with SOPs



New staff need to read and check off on comprehension using skills checklists

It's helpful to have a skills checklist that reflects each SOP, to ensure that onboarding training and skills refresher practice includes monitoring and documentation of any steps which may require remediation.



If your SOP tracker assumes they are reviewed annually - show documentation

A simple excel spreadsheet makes an excellent review cycle tracker for SOPs.

Remember that not all SOPs may require the same review cycle time: SOPs outlining high-acuity procedures, cross-department expectations or notification pathways may need a more frequent review cycle



Update your SOPs at the interval or intervals your institution requires but if there isn't a set requirement:

NIH SOP review expectations vary from every year to every 3 years, depending on the context and setting in which the SOP is utilized.

Ensure that the review cycle frequency keeps pace with how the rate at which potential changes may impact a procedure. For example, an SOP on how to open a door would need less frequent reviews than an SOP on how to open a door and that door receives modifications every 3 months.

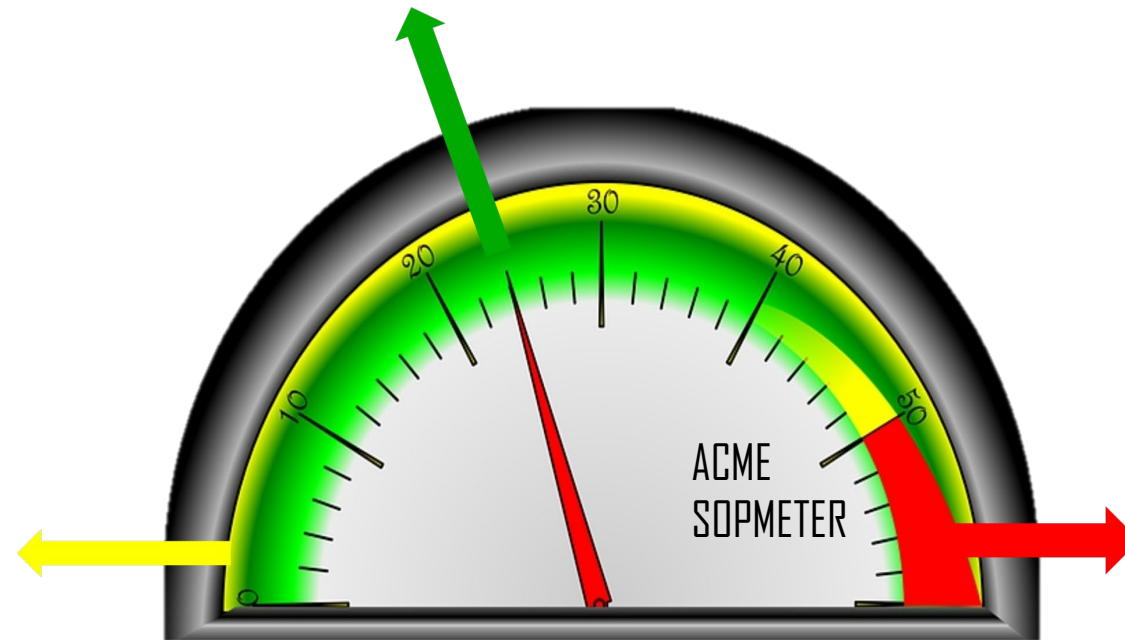
Reference for SOP Review Guidance

<https://www.niaid.nih.gov/sites/default/files/score-quality-management.pdf#:~:text=Standard%20Operating%20Procedures%20Requirements.%20%E2%80%A2%20CRSs%20must,as%20needed%20when%20a%20current%20process%20changes.>

How many is too many?

The correct amount of SOPs is not defined by a “number”. The ideal: as many SOPs as there are procedures or processes which must be done a specific way to achieve the specific outcome

Having too few SOPs, or focusing only on advanced or higher risk procedures leaves new or cross-trained employees at a disadvantage when it comes to mastering “basic” skills, as does creating a single overly complicated SOP that would be better as 3 individual



Having too many SOPs may look impressive, but the higher number of SOPs, the less likely staff will be to read any of them. Additionally, version control issues compound, and too many SOPs can negatively impact staff ability to navigate unexpected events

In Summary:

- PPE may exist in negative pressure, but not in a vacuum by itself: it is an extension of the layers of safety controls that comprise the design of your clinical or lab space.
- SOPs are important (and become more important relative to the level of potential instabilities in the environment needing standardization). They link concept to practical implementation, support consistency and reproducibility
- A strong library of SOPs, utilized as training assessments in the form of checklists, ensures that any instability or confusion does not originate within the staff, no creative decisions regarding PPE “choice” are given space unless in the context of an unexpected event.
- Don’t over complicate it: complicated environments can be simplified by creating accessible, understandable SOPs
- Procedures should include only what is necessary, and should be written in a way that does not constrain but to support consistency
- Advocate for the protections that you, as a subject matter expert in your own field, know you need in order to ensure high quality data outcomes from your work, as well as your own safety.



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