Personal protective equipment in animal research – back to the basics

A review paper

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Abbreviations and acronyms:

AAMI – Association for the Advancement of Medical Instrumentation AATCC - American Association of Textile Chemists and Colorists ANSI - American National Standards Institute
ASTM - American Society for Testing and Materials
BMBL - Biosafety in Microbiological and Biomedical Laboratories
CFR – Code of Federal Regulations
FDA – Food and Drug Administration
NFPA - National Fire Protection Association
NIOSH - National Institute of Occupational Safety and Health
OHSP - Occupational health and safety program
PAPR - powered air purifying respirator
PPE - personal protective equipment

Abstract

The occupational health and safety program (OHSP) is an integral component of an animal care and use program. Exposures of animal care and research personnel to allergens and physical, chemical, radiological, and biological hazards can occur in the conduct of various tasks, thus it is important to mitigate the risk of such exposures. This is especially true in infectious disease and biocontainment research. One aspect of the program is the provision of personal protective equipment (PPE). Commercially available PPE should be carefully evaluated based on its material composition and performance per manufacturer data. To help institutions and end users by providing them guidance on choosing appropriate PPE, this review paper discusses the regulatory framework, device standards, and materials engineering for various PPE, including gloves, shoe covers, head caps, gowns, aprons, masks, hearing and eye protection devices, and respirators. Ultimately, the choice of appropriate PPE is based upon the risk assessment, which should include consideration for personnel comfort, proper device fitting, and the containment level for the hazard used.

The use of animals in research comes with the innate risk of accidental exposure of personnel to various hazards. Animals produce allergens from body secretions and products including dander, urine and saliva. Meanwhile, chemicals like chlorine-based solutions and quaternary ammonium compounds are commonly used for environmental sanitation and disinfection. Others like bromodeoxyuridine and tricaine methanesulfonate, and radioactive substances such as bioimaging tracers are used for animal experimentation. Additionally, biohazards include causes of natural infections in animals (e.g., *Macacine herpesvirus 1* in macaques), infectious organisms used to model human disease, and more commonly, viral vectors used as a tool for gene delivery into cells. Finally, personnel exposure to high noise levels can occur during care of certain animal species or when using noise generating equipment such as cage and rack washers.

To mitigate exposure risks, a three-fold management approach is needed as enumerated in the *Guide for the Care and Use of Animals* (NRC, 2011). Thus, a robust occupational health and safety program (OHSP) can only be described in good terms when associated with these components. First, engineering controls entail appropriate safety equipment provision and facility design and operation. Second, administrative controls need to be implemented to clearly describe processes and standard operating procedures (SOPs). Finally, when exposure to hazards cannot be engineered completely out of normal operations and when safe work practices and other forms of administrative controls cannot provide sufficient additional protection, the use of personal protective equipment (PPE) provides a supplementary means of control and serves as the last line of defense for risk exposure. Clearly, education and training are embedded in these three components and will ensure full implementation of safety standards and practices, and personnel compliance. This review paper hopes to provide a reference for personnel on the selection and appropriate use of various PPE in full consideration of industry and regulatory standards. However, a thorough and comprehensive discussion of the standards is beyond the scope of this paper, and the reader is directed to the standards for more information.

Regulatory framework

The OSHA Act was promulgated to protect employees from the hazards in the workplace. The OSHA *Personal Protective Equipment Standard*, Subpart I 29 CFR § 1910.132 requires PPE to be selected based on the hazards present and provides workers with the appropriate protective equipment which must be worn to reduce the potential for harm and injury. The PPE standard includes protection for the eyes, face, head, feet and hands and specifically outlines the process for the selection of appropriate PPE, training on its use, and its replacement and disposal. As a general rule, PPE must be provided, used and maintained in reliable conditions whenever hazards in the workplace can cause injury or impairment from physical contact.[8] OSHA requires that many categories of PPE meet or be equivalent to standards developed by the American National Standards Institute (ANSI).[26] For respirators, the National Institute of Occupational Safety and Health (NIOSH) is the responsible organization for testing and certification.[13]

The *OSHA Bloodborne Pathogen Standard* 29 CFR § 1910.1030 also requires employers to provide and ensure employees use appropriate PPE such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks, and eye protection when handling human blood or other potentially infectious materials. With regard to contaminated PPE, OSHA has indicated that "home laundering is unacceptable because the employer cannot ensure that proper handling or laundering procedures are being followed and because contamination could migrate to the homes of employees".25 Employers are thus responsible for cleaning, laundering and/or disposing of personal protective equipment.10

Other pertinent OSHA standards include the *Respiratory Protection Standard* 29 CFR 1910.134 and *Occupational Noise Exposure Standard* 29 CFR 1910.95. The former was established to prevent potential occupational illnesses caused by exposure to airborne contaminants, including potentially infectious aerosols. Meanwhile, the latter was enacted to protect employees against the effects of high intensity occupational noise.
Specific to animal research, an OSHP should be established based on the guidelines described in the *Guide*, which outlines that the program be consistent with federal, state, and local regulations but also encourages institutions to tailor the specific needs, such as PPE, to its specific program.24 One of these foremost resources is the Biosafety in Microbiological and Biomedical Laboratories (BMBL) by the Centers for Disease Control Prevention (CDC)/ National Institute of Health (NIH). Considered to be the minimum standard of practice for all U.S. laboratories that handle infectious microorganisms and hazardous biological materials, the BMBL provides information on good work practices, proper PPE, safety equipment and laboratory facility design for each biosafety level. In particular, Table 3 of the BMBL summarizes recommended practices, PPE, and primary and secondary barrier characteristics.

Risk assessment

The first step in the selection of appropriate PPE is to conduct a risk assessment. Personnel should be evaluated based on several factors including the hazardous materials or equipment they will be working with as well as any special medical conditions like pregnancy, immune status, and ill health. For example, personnel with asthma may not likely be able to use N95 respirators because of their higher breathing resistance and should instead consider the use of a powered air purifying respirator (PAPR). Wearing

cultural and religious clothing like a headdress can also provide a unique opportunity to assess potential accommodations for personnel protection. Meanwhile, animal species with which personnel would be working also need to be considered. Certainly, working with nonhuman primates necessitates the use of additional PPE than what may be required in non-infectious research using mice. In this regard, PPE must be chosen based on the appropriate containment level as dictated by hazard identification.

Risk assessment, however, does not end with a questionnaire that will define and describe the personnel medical status, the animals being used, and the hazards personnel can be exposed to. Risk assessment also carefully evaluates the facility and its equipment and bridges the gap between engineering and administrative controls. As such, PPE can only be truly effective when used appropriately in the correct environment. For instance, full protective clothing can be worn for any procedure; however, the clothing itself will not offer complete protection if it is not donned and doffed properly. Meanwhile, when procedures are performed without equipment that will minimize risk exposure, additional PPE should be considered. For example, a respirator may be needed in addition to simple gown and gloves when changing rodent cages without the use of a cage changing station. Ultimately, PPE is to be used only as a supplement to, and not a replacement for, engineering standards and adequate administrative processes.[19,27]

Terminology

In describing the characteristics of various PPE, several terms need to be defined. It is important to note, however, that there is no industry consensus for using these terms. Thus, the Food and Drug Administration (FDA) does not approve marketing PPE (especially surgical gowns or drapes) with labeling claims using the terminology below. The manufacturers must then provide fabric or garment specifications associated with the standard test methods or standard classifications. For the purposes of this review paper, the following definitions are used:

- ***Fluid-resistant*** - protective clothing tested against water as the liquid challenge[22]
- ***Impermeable*** – material has been demonstrated blockage of microorganisms using a recognized standard test method[22]

PPE components

Aprons, Isolation gowns, Coveralls, and Sleeve protectors

OSHA requires that these PPE meet or be equivalent to the standards developed by ANSI. The standard developed by the Association for the Advancement of Medical Instrumentation (AAMI) and approved by ANSI for protective apparel is described in ANSI/AAMI PB70:2012 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* (PB70). This second edition establishes a system of classification for protective apparel and drapes used in health care facilities based on their liquid barrier performance. PB70 also specifies related labeling requirements and standardized test methods for determining compliance. Its scope covers all types of protective apparel that are labeled with liquid barrier claims or liquid borne microbial barrier claims (e.g., single-use and multiple-use surgical gowns, decontamination garments, isolation gowns, aprons, sleeve protectors, laboratory attire, and other garments) and that are regulated by the FDA as medical devices under

General and Plastic Surgery Devices.[9] Among those not covered by PB70 include protective apparel for the head, face, and eyes, and feet, such as face shields, surgical caps, surgical masks, respirators, and shoe covers. While device standards are primarily directed to the manufacturer, they may also be of value to the device purchaser or user as a frame of reference for device evaluation.[2]

There are a number of safety and performance characteristics of protective apparel based on PB70. These include barrier effectiveness, abrasion resistance, strength, comfort, aesthetic acceptability, electrostatic properties, flammability, and strike-through investigation. In fact, classification of barrier effectiveness based on resistance to liquid and microbial penetration (Table 1) was the primary reason for the development of PB70. Briefly, the liquid challenge is different with the various barrier performance levels because the surface tension of water is much higher than that of blood, so blood can penetrate through fabrics more readily than water. Consequently, levels 1, 2, and 3 test methods by the American Association of Textile Chemists and Colorists (AATCC) that use water as a challenge agent may not be representative for evaluating the barrier effectiveness of PPE and may overestimate the effectiveness of the PPE for blood-borne pathogens. Level 4 entails American Society for Testing and Materials (ASTM) F1670, which evaluates the surgical drapes material's resistance to synthetic blood penetration. Meanwhile, for surgical and isolation gowns, the viral penetration resistance test ASTM F1671, should be used. This uses the bacteriophage Phi-X174 because of its similar spherical morphology to human immunodeficiency, hepatitis B, and hepatitis C. At 27 nm in diameter, it is similar in size to hepatitis C (30 nm diameter), the smallest-known blood-borne viral pathogen.

Another standard frequently utilized in the United States is the NFPA® 1999: *Standard on Protective Clothing and Ensembles for Emergency Medical Operations* (NFPA® 1999) by the National Fire Protection Association (NFPA). The 5th edition released in 2013 specifies minimum documentation, design, performance, testing, and certification requirements for new single-use and new multiple-use emergency medical operations protective clothing used by emergency medical responders prior to arrival at medical care facilities, and used by medical first receivers at medical care facilities during emergency medical operations.[21] The NFPA® 1999 supports ASTM F1671 as the standard test for the barrier material and barrier layer seams used.[21]

The AAMI Protective Barriers Committee also developed the technical information report AAMI TIR11:2005 *Selection and use of protective apparel and surgical drapes in health care facilities* (TIR11) to produce a reference that would enhance excellence in patient care practices involving protective apparel and drapes.[1] First issued in 1994, this document covers the selection and use of protective apparel and surgical drapes. It includes information on types of protective materials, safety and performance characteristics of protective materials, product evaluation and selection, levels of barrier performance, and care of protective apparel and drapes. A table in the report suggests barrier performance levels in accordance with PB70 for several patient care procedures based on anticipated exposure risks (see Table 2).

The barrier performance of protective apparel depends on the material composition and how the fabric was created. Polypropylene and polyethylene are the primary components of protective apparel (Table 2). Those made from spunbonded polypropylene (PP), while naturally low in lint, offer basic cover protection. When a

fabric is spunbonded, the filaments have been extruded, drawn and laid on a moving screen to form a web.[3] The fabric can also be made of multi-ply polypropylene, when it consists of inner layers of meltblown polypropylene sandwiched between outer layers of spunbond polypropylene. When meltblown, the fabric has polymer resins that are extruded and drawn molten with heated, high velocity air to form fine filaments. The filaments are cooled and collected as a web onto a moving screen. The process is similar to the spunbond process, but meltblown fibers are much finer and generally measured in microns.[3] Finally, when the fabric is flash-spun, as in the case of Tyvek® material which is a high-density polyethylene (HDPE), the nondirectional fibers (plexifilaments) are first spun and then bonded together by heat and pressure, without binders.[16] HDPE has little branching as compared to other polyethylene, giving it stronger intermolecular forces and tensile strength than low-density polyethylene (LDPE). The difference in strength exceeds the difference in density, giving HDPE a higher specific strength making the fabric itself able to stand abrasion or being worn away. However, HDPE, and monolithic films, can easily be cut with scissors or a knife.

Fabric can be woven or nonwoven, with the former being stronger and higher quality than the latter due to the layers created by the threads woven over and under one another. However, nonwoven materials are generally more affordable because they are cheaper and faster to manufacture. Finally, seam production differs among protective apparel. Serged seams are produced when the threads are interlocked around the material edges for a strong stress-resistant seam. In contrast, in ultrasonic welded seams, there are no thread or needle holes with this seam. The material is welded together creating an excellent particle and fluid barrier.

The requirements for the design and construction of protective apparel are based on the anticipated location and degree of liquid contact during expected use. In particular, critical zones of surgical and isolation gowns are identified as those where direct contact with blood, body fluids, and/or other potentially infectious materials is most likely to occur (Figure 1). Apparel that can be used for general purpose includes gowns made from spunbond polypropylene and gowns that are apron-style with over-the-head neck, waist ties and thumb loop wrists (Figure 2). Both do not meet AAMI PB70 standard for isolation gowns, as barrier performance of at least level 1 is required for the entire gown (areas A, B, and C in Figure 1), including seams but excluding cuffs, hems, and bindings. Isolation gowns include those made from microporous laminate fabric and multi-ply polypropelene. Coveralls, sometimes generally referred to by the brand name Tyvek® suit, is a type of isolation apparel commonly used in higher biocontainment levels. Less commonly known materials that still meet AAMI Level 4 for barrier protection are monolilthic films. For ABSL4 procedures, a one-piece positive pressure suit ventilated with a life support system must be used to conduct all procedures.[14] This suit, with clear, flexible 360° hood, is supplied with fresh, filtered air via overhead tubing.

In choosing protective apparel, careful review of the manufacturer-provided information related to the barrier performance of each critical zone component is warranted. Once the suitable type of apparel is identified, personnel need to determine the appropriate size for individual needs. For coveralls, especially those with attached boot covers and hood, this is typically one size up than the person's body size to allow for flexibility in movement. An undersized suit may compromise an individual's comfort and barrier integrity, especially if the fabric or seams and barrier layer on the

fabric is not durable enough to withstand typical stresses applied during wear or use, such that garments may tear during kneeling, reaching, or bending. Meanwhile, oversized apparel may cause accidents like tripping.

Sleeve protectors or covers, typically around 16”-18” long, tapered, tunneled elastic at both ends, are used to cover the arm or garment’s sleeve from the wrist extending beyond the elbow area. They could be used alone to protect the arms of personnel wearing scrubs and gloves; such PPE ensemble may be sufficient when working with animals not requiring containment housing while using engineering standards like animal transfer stations and individually ventilated cages. They could be used, however, over a gown or coveralls for procedures with high potential of aerosol exposure (e.g., necropsy or working with vomiting patients).

Gloves

Gloves, the most commonly used PPE, is primarily used to prevent exposure of the individual to the hazard as well as to reduce the risk of environmental and product contamination. Currently, ANSI does not have a standard for gloves; however, OSHA recommends that selection be based upon the tasks to be performed and the performance and construction characteristics of the glove material.[26] Medical gloves are class I (general controls) reserved devices and are subject to general controls of the Federal Food, Drug, and Cosmetic Act.

The FDA issued the *Medical Glove Guidance Manual* in 2008 to provide recommendations for premarket notification submissions and compliance with the quality system regulation for medical gloves. In this manual, patient examination gloves are classified into 5 subcategories – latex, vinyl (PVC), polymer (other than vinyl and includes nitrile and polyurethane), finger cot, and specialty (includes chemotherapy).[17] The manual also describes types of gloves (surgeon’s, radiographic protection, and non- medical like food and cleaning gloves) other than patient examination gloves, and these include Kevlar® and leather gloves that may be used on top of examination gloves and are cut-resistant, and cryogenic gloves, which are multilayered insulated designed to prevent thermal injury. This section however, will only focus on the three most commonly used types of patient examination gloves as presented in Table 3.

Manufacturers of gloves, specifically surgeon’s gloves, need to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.[11] The design specifications, as described by the FDA manual, should include glove performance and efficacy; human factors such as fatigue and donning; glove length, cuff, size, and thickness; chemical safety, biocompatibility,
environmental compatibility, and allergenicity (protein levels) of the glove material; pinhole acceptable quality level; and glove compatibility with blood, saline and any intended chemical contact. The FDA also considers shelf life to be a significant factor in meeting user needs. Design validation, conducted under real or simulated conditions to determine whether the device meets user needs, assures that the donning ability, strength, thickness, feel, size, shape, texture, holding ability, tactile sensitivity, lack of fatigue, lack of irritation, color, and odor of the gloves are satisfactory to users.[17] Medical grade gloves have the label “Exam” or “Medical Grade” clearly marked on the packaging, which means they

are FDA approved for medical use. These gloves, however, are typically not intended to be used as a chemical barrier.

Lubricants facilitate donning of medical gloves. Gloves with powdered lubricants, also called donning or dusting powders, are not recommended since powder can react with commonly available alcohol-based handrubs. In March 2016, the FDA proposed a ban on most powdered medical gloves based on its review of scientific literature and comments related to risks and benefits of such gloves.[18] The ban specifically indicated that aerosolized glove powder on natural rubber latex gloves can carry proteins that may cause respiratory allergic reactions. All types of powdered gloves, including synthetic rubber, have also been associated with other adverse events like severe airway inflammation, wound inflammation, and post-surgical adhesions.[18] Alternatively, powder-free gloves with an inner coating enhanced with a small amount of silicone or with aloe lining should be used. Gloving creams to lubricate the user's hand are also available and are classified as a class I device by the FDA. As a general rule, oil-based creams should not be used as they will degrade the glove material (especially f latex gloves).[17] Other than immune reaction to powder and latex proteins, sweat and moisture may have an irritant action as well. Additionally the friction associated with wearing or removing gloves may also contribute to dermatitis of the hands.[6]

Regular length gloves are usually sufficient for general work in animal research. However, using extended cuff gloves to cover the sleeves or cuffs of the gown or coveralls is advocated when there is a high risk of hazard exposure, as in the case of working in infectious disease research or working with animals like nonhuman primates that may carry debilitating zoonotic diseases. Similarly, double gloving has proven to be more effective in reducing self-contamination than single gloving.28 In fact, blood volume on a solid suture needle is reduced as much as 95% when passing through two glove layers, thereby reducing the viral load in the event of a contaminated percutaneous injury.5 For double gloving, a color-coded system for inner and outer gloves may be considered for safety and compliance. Color-coded gloves can also help to differentiate sizing, prevent cross contamination, or designate various types of glove material. In addition, it may help identify a breach in the glove, for instance when the inner glove color is visible due to a pinhole or tear in the outer glove. It is important that personnel do not have the false security that wearing gloves is sufficient to prevent hazard exposure. Hand hygiene is necessary as contamination may occur via small defects in gloves or during doffing. Variations in production processes may also significantly affect glove properties like abrasion resistance.29 Additionally, the use of alcohol-based disinfectants with latex or synthetic gloves has been shown to permeate or degrade gloves such that the safety may be compromised.4

Head caps and boot/shoe covers

The Occupational Safety and Health Standards indicate that surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopedic surgery).30 Additionally, the BMBL indicates that boots, shoe covers, or other protective footwear, are to be used, where indicated, to conduct ABSL3 procedures.14 However, as shoe covers do not improve bioexclusion and may actually compromise it due to contamination potential of personnel from contact with shoe bottoms during donning,20 this PPE may be unnecessary for ABSL1 procedures, especially with the common use of microisolation

caging and ventilated rack housing for rodents. The NFPA® 1999 indicates that ASTM F1671 be used for testing footwear materials and footwear cover materials.21 Commonly used head caps and shoe covers are made of polypropylene. As in Table 2, this may be spunbonded, multi-ply, or coated. For head caps, either bouffant or surgeon's caps can be used. While bouffant caps are made of one material, the fabric for surgeon's caps is divided into the side and crown material. Crown material is typically made of polypropylene; while side materials can be scrim reinforced material (a paperlike absorbent material), multi-layer polypropylene, or spunlace. A surgeon's hood, with or without beard covers and typically made of polypropylene as well, can be used to provide complete head coverage. For shoe covers (Figure 3), durability and anti-skid properties are important. Boot covers that can extend up to the knees can also be used and should be considered when performing procedures that may involve heavy floor soiling (e.g., washing NHP cages). Shoe covers made of low-density polyethylene, while with less traction because of its smooth bottom, resist high levels of fluid. Those made from coated polypropylene and high-density polyethylene, among others, pass ASTM F1671.

Masks and Respirators

Respiratory protection is a big component of the PPE ensemble in infectious disease research especially for hazards with a potential for aerosolization. As such, personnel must wear appropriate respiratory protection[14] or positive pressure suit[14] as described above for biocontainment levels 3 and 4, respectively. For ABSL2 procedures, respiratory protection should be used in rooms containing infected animals, as dictated by the risk assessment.[14] These requirements are in accordance with the Occupational Health and Safety Standards indicating that masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.[10]

In 2001, NIOSH created the National Personal Protective Technology Laboratory (NPPTL) with one of its primary functions being to carry out testing procedures and recommend respirators for approval. Thus, the respirator must be NIOSH-approved as in accordance with *Approval of Respiratory Protective Devices* 42 CFR Part 84 and meet the requirements of ASTM F2100, *Standard Specification for Performance of Materials Used in Medical Face Masks*. The FDA also regulates surgical masks and surgical N-95 respirators. As an example of labeling, when a respirator is cleared by the FDA as a surgical mask and certified by NIOSH as an N-95 respirator mask, the FDA calls it a "*surgical N-95 respirator*."

The *Annex A Explanatory Material* of the NFPA® 1999, although created as a reference (i.e., not a part of the standard) for patient care providers, provides useful information on the use of surgical masks and respirators (Figure 4). Typical surgical masks, which are made of polypropylene and feature three pleats/folds to allow the user to expand the mask, or are made of synthetic polyester and molded with an adjustable aluminum nosepiece, which cover from the nose to under the chin of the wearer. Not covered by NIOSH, they are not designed or certified to prevent the inhalation of small airborne contaminants. However, they are worn to help prevent patient exposure to the wearer's saliva and respiratory

secretions and help protect the wearer against splashes of large droplets of potentially infected fluids like blood. The other commonly used mask for patient care is N-95 respirators, which entail medical clearance and fit testing to form a tight seal over the mouth and nose to ensure efficacy. N-95 respirators filter out at least 95 percent of airborne particles during "worse case" testing using a "most-penetrating" sized particle.[21] Other kinds of respirators include those that filter out at least 99 percent and at least 99.97 percent (essentially 100 percent) of airborne particles, which receive "99" and "100" rating, respectively. Disposable respirators are also further rated for protection against oils, as some industrial oils can degrade filter performance. "N" respirators are not resistant to oil; "R" if somewhat resistant to oil; and "P" if strongly resistant (oil proof). Thus, there are nine types of disposable respirators according to percent filtration and oil resistance.

Half- and full-facepiece elastomeric respirators are tight-fitting, air-purifying respirators with replaceable filters (for particulates) or cartridges or canisters (for gases and vapors), which are attached to a rubber or silicone facepiece that covers at least the nose and mouth. These need to be fit tested and can be cleaned, decontaminated, and reused. One advantage of the full facepiece respirator is its high level of protection because of its sealing properties, especially that it also covers the user's eyes and face. An alternative to the use of disposable and elastomeric respirators is the loose-fitting PAPR, which is battery-operated and consists of a facepiece mask, helmet or hood, breathing tube, battery-operated blower, and HEPA filters. As it is less restrictive, it provides a good option for individuals with facial hair or unusual facial features, which make respirator fitting difficult, or those with medical conditions like asthma. It is also more comfortable to wear in biocontainment facilities as it provide a cooling effect in the hood and offers less breathing resistance compared to a standard tight fitting respirator. PAPRs provide a higher level of protection than most disposable respirators, as it is as efficient as P-100 respirators.[21] A PAPR uses a blower to pass contaminated air through a HEPA filter, which removes the contaminant and supplies purified air to a facepiece. Some models use two shrouds, with one that needs to be tucked under the protective garment (typically coveralls). This inner shroud channels excess air into the garment and over the body for additional comfort. The reusable elements of PAPRs should be cleaned and disinfected after use. The filters should be considered contaminated with infectious material, and discarded safely when being replaced in accordance with manufacturer's recommendations.

Eye and Face Protection

Eye and face protection is advised whenever the potential exists for exposure through splash, spray or splatter of potentially infectious biological materials to the eyes, nose, or mouth. For ABSL1 and ABSL2 procedures, eye and face protection should be used in rooms containing infected animals, as dictated by the risk assessment.[14] Regular prescription glasses do not provide adequate eye protection, therefore safety glasses made of hardened-glass or plastic, should be considered minimal eye protection and worn to prevent injury from projectiles, minor splashes

or contact of contaminated hands with eyes.[24] It is also advised that individuals who wear contact lenses should wear eye protection.

Most safety glass lenses today are made of polycarbonate, or varieties of this material, or the traditional hardened safety glass. However, polycarbonate lenses are typically more impact-resistant than glass lenses. Safety glasses must have side shields and should be chosen to conform to the wearers face, minimizing gaps around the glasses where materials may enter the unprotected eye. Safety goggles should be worn when there is a hazard from splashing, especially from corrosive chemicals that could be injurious to the eye, such as concentrated chlorine or phenolic disinfectants, or from flying objects or particles. All protective eye and face protection must comply with the ANSI *Standard for Occupational and Educational Eye and Face Protection* (ANSI Z87.) Both safety glasses and goggle lenses are susceptible to fogging as a result of increased body temperature during exertion and environmental factors such as heat and humidity. Lenses with anti-fog coating that is applied to both the inside and outside of the lens should be a consideration in selection of eyewear. Another option includes the dual-pane lens, which consists of an air pocket between two layers of lens. This helps balance the temperature between the front of the eyewear and the back. Face shields, splash goggles worn with mask, or masks with a built-in eye shield offer greater protection to the face and neck area. In order to ensure full protection, safety glasses or goggles should be worn in combination with the face shield. It is important to remember that any device that is to be reused must be properly decontaminated.

Ear protection

The noise level in animal facility areas may reach potentially damaging levels, depending on the animal species being used (particularly pigs and dogs), the animal related procedure, and the type of equipment being used (especially cage washing areas). The use of special equipment like an ultrasound machine that may produce sound not audible to people may also result in hearing damage and may be covered through ANSI standards. In fact, if the frequency is below 20 kHz for ultrasonography it is covered by the OSHA noise standard.[24] If exposure to high noise levels cannot be minimized through facility design or administrative controls such as decreased exposure time, wearing hearing protectors like earmuffs or earplugs is required. OSHA limits employee exposure to noise to 90 dBA averaged over an 8-hr work shift.[7] Where levels exceed 85 dBA, exposed employees need to participate in a hearing conservation program that includes monitoring, audiometric testing, hearing protection, training, and record-keeping.[7]

Hearing protectors must be carefully selected to ensure it provides the correct noise attenuation especially that there is no single type of hearing protection that works for all individuals or situations. Some factors that should be considered when selecting protectors include individual comfort, size of ear canal, noise environments, work activities, and environmental conditions. The most common types of hearing protectors include earplugs and earmuffs. Foam earplugs, most commonly used by animal care staff, provide adequate noise reduction, and are convenient and comfortable to use. However, they can be hard

to fit properly especially for an individual with a smaller ear canal. An alternative device would be the molded or flanged plug, which come in a variety of sizes for individual fit and are easy to insert into the ear canal. Earmuffs that seal against the head and directly over the outer ear are designed with a foam or fluid material that is enclosed in an outer plastic envelope. Advantages include one size fits most individuals and greater hearing protection. However, they can be uncomfortable to wear in hot work areas and can restrict head motion.

Conclusion

There are many considerations in implementing the institutional PPE requirements. With the aim of meeting compliance with regulatory agencies and adhering to best practice, PPE should be primarily selected based on risk assessment, level of containment involved, and its material composition, which dictates the level of barrier performance it provides. Additional consideration must be given to the proper fit and comfort.[26] The manner in which the clothing is donned and doffed in sequence with other PPE is also important because the ease or difficulty with which this process is done may affect its effectiveness and the potential for self-contamination during doffing. A buddy system and/or the use of a step-by-step checklist may be considered for high-risk procedures. The requirements and all pertinent processes should be described in a standard operating procedure (SOP) document that is used for training. Documentation of training for proficiency and competency in donning and doffing is necessary for higher biocontainment work. The training needs to include what PPE to use and its limitations, when and where to use it, how to properly don, doff, adjust, and wear it; and its proper care, maintenance, and disposal.[8] Periodic assessment of efficacy and applicability, together with SOP review, is recommended. Although an integral component of the institutional health and safety program, the use of PPE alone will not provide full
protection against hazard exposure. Other practices such as good hygiene and laboratory techniques, use of specialized instruments, supplies, and building infrastructure, and vaccinations, as appropriate, complement risk mitigation.

References

1. Association for the Advancement of Medical Instrumentation. 2005. TIR11:2005 Selection and use of protective apparel and surgical drapes in health care facilities. Arlington, VA.
2. Association for the Advancement of Medical Instrumentation. 2012. ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Arlington, VA.
3. Association of the Nonwoven Fabrics Industry. [Internet] 2012. Spunbond and Melt Blown Technology. [Cited 20 October 2016] Available at http://www.inda.org/spunbond-melt-blown.html.
4. Baumann MA, Rath B, Fischer JH, Iffland R. 2000. The permeability of dental procedure and examination gloves by an alcohol based disinfectant. Dent Mater **16**(2):139-44.
5. Bennett NT, Howard RJ. 1994. Quantity of blood inoculated in a needlestick injury from suture needles. J Am Coll Surg **178**:107–110.

6. Centers for Disease Control and Prevention. [Internet] 2002. Morbidity and Mortality Weekly Report: Guideline for Hand Hygiene in Health-Care Settings. [Cited 20 October 2016] Available at http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf.
7. Code of Federal Regulations (CFR). 1974. Title 29, Part 1910. Occupational Safety and Health Standards; Subpart G, Occupational Health and Environmental Control; Standard number 1910.95, Occupational noise exposure. Washington: Office of the Federal Register. Available at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9735.
8. CFR. 1974. Title 29, Part 1910. Occupational Safety and Health Standards; Subpart I, Personal Protective Equipment. Washington: Office of the Federal Register. Available at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDA RDS&p_id=10118.
9. CFR. 1988. Title 21 Part 878. General and Plastic Surgery Devices. Washington: Office of the Federal Register. Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=878.
10. CFR. 1991. Title 29, Part 1910. Occupational Safety and Health Standards; Subpart Z, Toxic and Hazardous Substances; Standard number 1910.1030, Bloodborne pathogens. Washington: Office of the Federal Register. Available at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051.
11. CFR. 1996. Title 21 Part 820.30. Design controls. Washington: Office of the Federal Register. Available at https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol8/pdf/CFR-2012-title21-vol8-sec820-30.pdf.
12. CFR. 1997. Title 21 Part 801.437. User labeling for devices that contain natural rubber. Washington: Office of the Federal Register. Available at https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol8/pdf/CFR-2012-title21- vol8-sec801-437.pdf.
13. CFR. 2004. Title 42, Part 84. Approval of Respiratory Protective Devices. Washington: Office of the Federal Register. Available at https://www.gpo.gov/fdsys/pkg/CFR-2012-title42-vol1/pdf/CFR-2012-title42- vol1-chapI-subchapG.pdf.
14. Department of Health and Human Services. 2009. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. Chosewood LC, Wilson DE, eds. Washington: Government Printing Office. [Cited 20 October 2016] Available at http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf.
15. Department of Energy. [Internet] 2013. Glove Selection Guideline. [Cited 20 October 2016] Available at http://www.aps.anl.gov/Safety_and_Training/User_Safety/gloveselection.html.
16. Dupont™ [Internet] 2002. Product Handbook of Dupont™ Tyvek®. [Cited 20 October 2016] Available at

http://www.dupont.com/content/dam/dupont/products-and-services/fabrics-fibers- and-nonwovens/industrial-fabrics/documents/DPT_Tyvek_Product_Handbook.pdf.

17. Food and Drug Administration. [Internet] 2008. Guidance for Industry and FDA Staff: Medical Glove Guidance Manual. [Cited 20 October 2016] Available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm428191.pdf.
18. Food and Drug Administration. [Internet] 2016. FDA proposes ban on most powdered medical gloves. [Cited 20 October 2016] Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491466.htm.
19. Harrison DJ. 2001. Controlling exposure to laboratory animal allergens. ILAR J **42**:17-36.
20. Hickman-Davis JM, Nicolaus ML, Petty JM, Harrison DM, Bergdall VK. 2012. Effectiveness of shoe covers for bioexclusion within an animal facility. J Am Assoc Lab Anim Sci **51**(2):181-8.
21. National Fire Protection Association. 2013. NFPA® 1999: Standard on Protective Clothing and Ensembles for Emergency Medical Operations. Quincy, MA.
22. National Institute for Occupational Safety and Health. [Internet] 2016. Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids. [Cited 20 October 2016] Available at https://www.cdc.gov/niosh/npptl/topics/protectiveclothing/.
23. National Research Council. 1997. Occupational Health and Safety in the Care and Use of Research Animals. Washington, DC: National Academy Press.
24. National Research Council. 2011. Guide for the Care and Use of Laboratory Animal Species. Washington, DC: National Academy Press.
25. Occupational Health and Safety Administration. [Internet] 2001. CPL 02-02-069: Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens. [Cited 20 October 2016] Available at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=2570.
26. Occupational Health and Safety Administration. [Internet] 2004. OSHA 3151-12R: Personal Protective Equipment. [Cited 20 October 2016] Available at https://www.osha.gov/Publications/osha3151.pdf.
27. Reeb-Whitaker CK, Harrison, DJ, Jones RB, Kacergis JB, Myers DD, Paigen B. 1999. Control strategies for aeroallergens in an animal facility. J Allergy Clin Immunol **103**:139-146.
28. Verbeek JH1, Ijaz S, Mischke C, Ruotsalainen JH, Mäkelä E, Neuvonen K, Edmond MB, Sauni R, Kilinc Balci FS, Mihalache RC. 2016. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Cochrane Database Syst Rev **4**: CD011621.
29. Walsh DL, Schwerin MR, Kisielewski RW, Kotz RM, Chaput MP, Varney GW, To TM. 2004. Abrasion resistance of medical glove materials. J Biomed Mater Res B Appl Biomater **15;** 68(1): 81-7.

Figure 1. Critical (grey) zones of an (A) isolation gown and (B) a surgical gown (B). The entire isolation gown (areas A, B, and C), including seams but excluding cuffs, hems, and bindings, is required to have a barrier performance of at least Level 1. In contrast, only the entire front of the surgical gown (areas A, B, and C) is required to have a barrier performance of at least Level 1. Note: The illustrations are not intended to reflect specific products or designs. *Adopted with permission from ANSI/AAMI PB70:2012.*

Figure 2. Protective apparel. (A) Spunbond multi-ply polypropylene gown; (B) apron-style polyethylene gown. The polypropylene gown offers basic protection and the polyethylene gown has an open back, so neither meets the PB70 standard for isolation gowns, but the (C) Surgical gown made of multilayered spunbonded-meltblown-spunbonded (SMS) fabric; (D) Flash-spun, high-density polyethylene (Tyvek®) suit. *Model is Ms. LaJuanda Carter of the Unit for Laboratory Animal Medicine, University of Michigan.*

Figure 3. Shoe covers made of (A) polypropylene with non-skid soles, and (B) polyethylene (B), and (C) boot covers made of flash-spun high-density polyethylene (Tyvek®).

Figure 4. Masks and respirators. (A) Three-pleated surgical mask; (B) surgical molded mask; (C) and(D) N95 respirators with a metal band that seals the nose bridge area (Note: on a high nose arch or a thin nose, the metal band does not work as well and may interefere with fit tests); (E) Flexible fit design N95 offers a pinch–free molded nose bridge for facial features that may not fit well with the other models; (F) half-facepiece respirator with HEPA filter cartridge r; (G) full-facepiece respirator with HEPA filter cartridge; (H) powered air purifying respirator (PAPR) with HEPA filter cartridge within helmet. *Model is Mr. Josh Bennett of the Department of Occupational Safety and Environmental Health, University of Michigan.*

Level [1]	Test	Liquid challenge	Result	Expected barrier effectiveness	Examples of procedures with anticipated exposure risks[2]
1	AATCC 42 *Impact Penetration*[3]	Water	≤ 4.5 g	Minimal water resistance (some resistance to water spray)	Simple excisional biopsies Excision of "lumps and bumps" Ophthalmological procedures Simple ear, nose, and throat (ENT) Procedures
2	AATCC 42 *Impact Penetration*	Water	≤ 1.0 g	Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)	Tonsillectomies and adenoidectomies Endoscopic gastrointestinal procedures Simple orthopedic procedures with tourniquets Open hernia repair Minimally invasive surgery Interventional radiology or catheter lab Procedures
	AATCC 127 *Hydrostatic Pressure*[4]	Water	≥ 20 cm		
3	AATCC 42 *Impact Penetration*	Water	≤ 1.0 g	Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)	Mastectomies Arthroscopic orthopedic procedures Endoscopic urological procedures (e.g., transurethral prostate resections) Open gastrointestinal and genito-urinary Procedures
	AATCC 127 *Hydrostatic Pressure*	Water	≥ 50 cm		
4	ASTM F1670 *Synthetic Blood Penetration Test* (for surgical drapes)[5]	Surrogate Blood	no penetration at 2 psi(13.8 kPa)	Blood and viral penetration resistance (2 psi)	Any procedure in which the surgeon's hands and arms are in a body cavity Orthopedic procedures without a tourniquet Open cardiovascular or thoracic procedures Trauma procedures Caesarean sections
	ASTM F1671 *Viral Penetration Test* (for surgical and isolation	Bacteriophage Phi-X174	no penetration at 2 psi(13.8 kPa)		

	gowns)[6]				

Table 1. Classification of barrier performance of surgical gowns, other protective apparel,
surgical drapes and drape accessories according to ANSI/AAMI PB70:2012 with examples of procedures from AAMI TIR11:2005. *Adapted with permission from AAMI.*
1In order of increasing protection.
2Examples are only general suggestions and should not be interpreted as absolutes or policy statements.
3American Association of Textile Chemists and Colorists (AATCC) 42 determines the ability of a material to resist water penetration under spray impact.
4AATCC 127 determines the ability of a material to resist water penetration under constant contact with increasing pressure.
5 American Society for Testing and Materials (ASTM) F1670, similar to ISO 16603, determines the ability of a material to resist the penetration of synthetic blood under constant contact.
6ASTM F1671, similar to ISO 16604, determines the ability of a material to resist the penetration of a microorganism under constant contact. This is standard test for the barrier layer material and barrier layer seams used in the construction of garments, work gloves, face protection devices, footwear, and footwear cover (NFPA 1999).

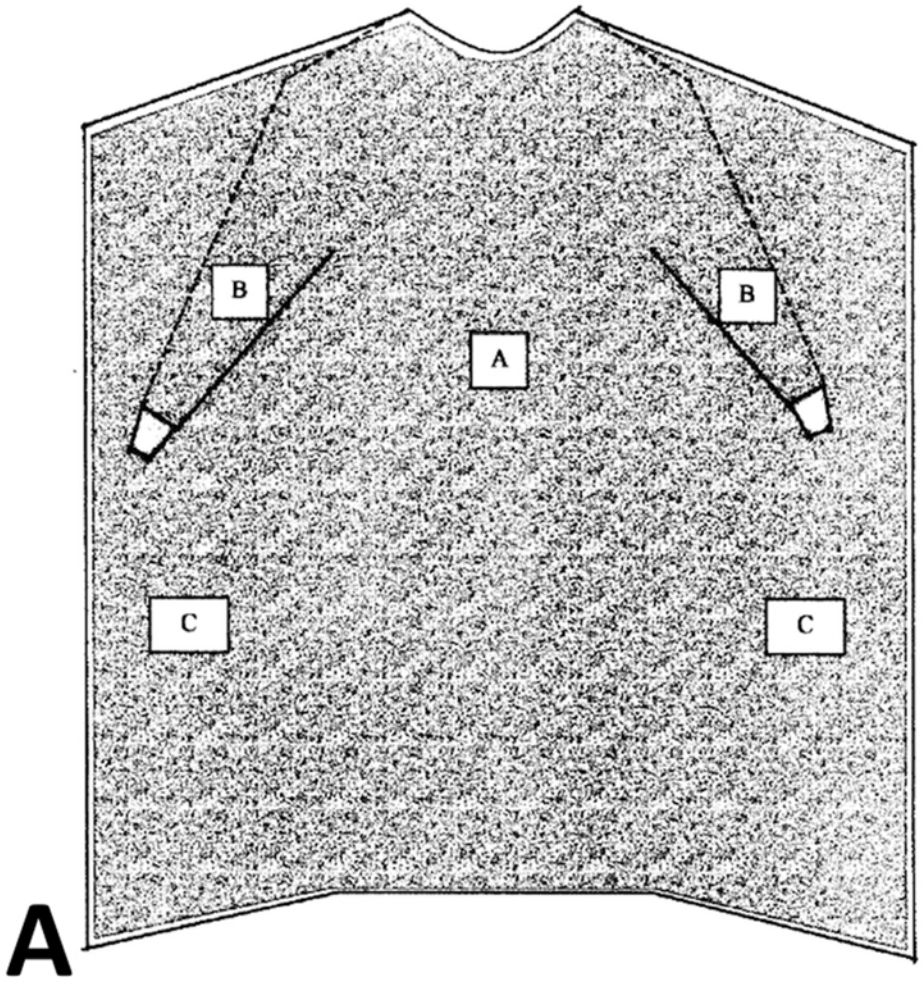
Material	Characteristics	Uses	Material Examples[1]
Spunbonded polypropylene	Economical, maximum breathability, strong, lightweight, low linting, not liquid resistant	Protects against dirt, grime, and certain dry particulates in nonhazardous environments, ideal for less critical areas or pre-gowning entry rooms, food processing environment, general purpose	• VWR® Basic Protection SPP Lab Coats
Multi-ply polypropylene	Densely packed meltblown layers sandwiched between strong, spunbond outer layers, come in multiple weights, may be liquid resistant, low linting	General purposes or isolation[2]	• Medline medium weight and lightweight polypropylene gowns (Figure 2A)
Low-density polyethylene	Low cost, waterproof protection for light duty, convenient, flexible	General purposes depending on the design (see apron-style)	• Medline Thumbs Up® polyethylene gown (Figure 2B)
Multilayered spunbonded-meltblown-spunbonded (SMS) fabric	High tensile strength, soft, comfortable, and breathable; low-linting and resistant to tears and punctures	Light fluid and particulate barrier	• VWR® Basic Protection SMS Coveralls • Medline Eclipse® Surgical Gowns
Flash-spun, high-density polyethylene	Light-weight, excellent abrasion resistance, expensive	Against hazardous dry particles and aerosols, and nonhazardous light liquid splash, isolation[2]	• DuPont™ Tyvek® (Figure 2D)
Monolithic film[2] made from co-polyesters	Good to very good breathability, no voids or holes in these types of films), high liquid repellency, and excellent comfort when bonded to PET nonwovens or glued to PP nonwovens	Isolation[3]	• DuPont™ HyTrel® • DSM Arnitel®
Microporous film laminated	High degree strength, Good dust and liquid repellent, great breathability	Isolation[3]	• VWR® Advanced Protection Coveralls • Kimberly-Clark KleenGuard* A40 • Kappler ProVent® 10000

Spunbonded polypropylene with polyethylene coating	Comfort and flexibility during use and protection against fine sprays and particles, Lightweight, low linting and hard-wearing material	Isolation[3]	• VWR® BioClean-D™, Clean-Tough™ • Medline medium weight and heavyweight coated isolation gowns

Table 2. Common materials used for manufacturing protective apparel.
1Review of manufacturer information is needed. Final determination of the use of the PPE needs to be in consultation with the institutional occupational health and safety unit.
2Isolation apparel needs to have at least a level 1 barrier performance for its entire area.
3Monolithic film is a polymer film, usually of urethane or co-polyester material, which can pass water vapor but does not have physical voids or cells.

	Nature of the material	Advantages	Disadvantages	Comment
Latex	Natural rubber	Comfort and fit, dexterity (high level of touch sensitivity), elastic and strong, easy to put on, biodegradable, low cost	Can cause latex allergy,[1] poor for organic solvents, little chemical protection, hard to detect puncture holes, frequently imported, may be poor quality	Petroleum-based hand lotions or creams may adversely affect the integrity of the gloves
Nitrile	Synthetic, acrylonitrile butadiene rubber	Comfort and fit, dexterity (high level of touch sensitivity), superiority to puncture resistance, clear indication of tears and breaks, resists many chemicals, long shelf life	More expensive than latex and vinyl	Chemical accelerators and other additives commonly used in production may elicit allergy symptoms in sensitive individuals.
Vinyl	Synthetic, polyvinyl chloride (PVC)	Less expensive, with anti-static properties, easy to put on	Less durable, limited dexterity, looser fit, plasticizers can be stripped; frequently imported may be poor quality, non-biodegradable	Popular in industries (e.g., food) where high levels of durability and protection are less of a priority

Table 3. Comparison of three commonly used types of gloves in health care and biomedical research settings. Summarized from US Department of Energy (2013) and Occupational Health and Safety Administration (2004).
1Natural rubber latex gloves are *misbranded* when it do not include the statement "*Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.*", as required by *User labeling for devices that contain natural rubber* 21 CFR 801.437.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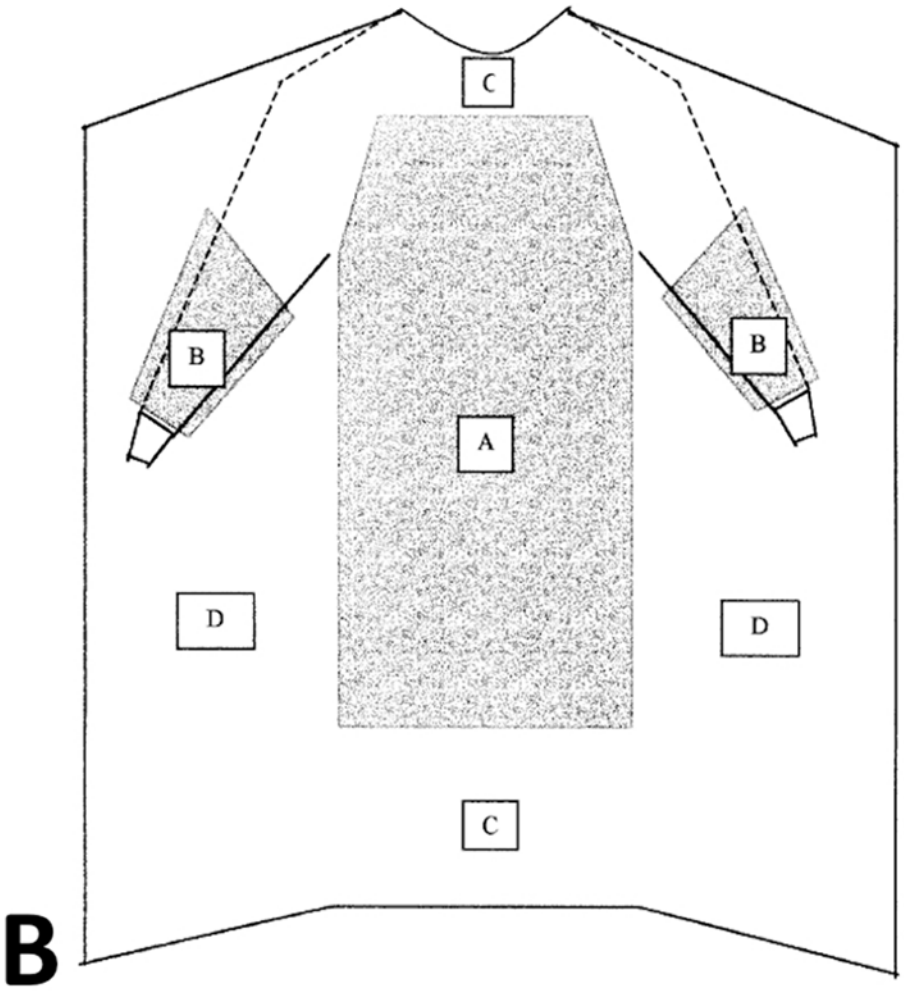
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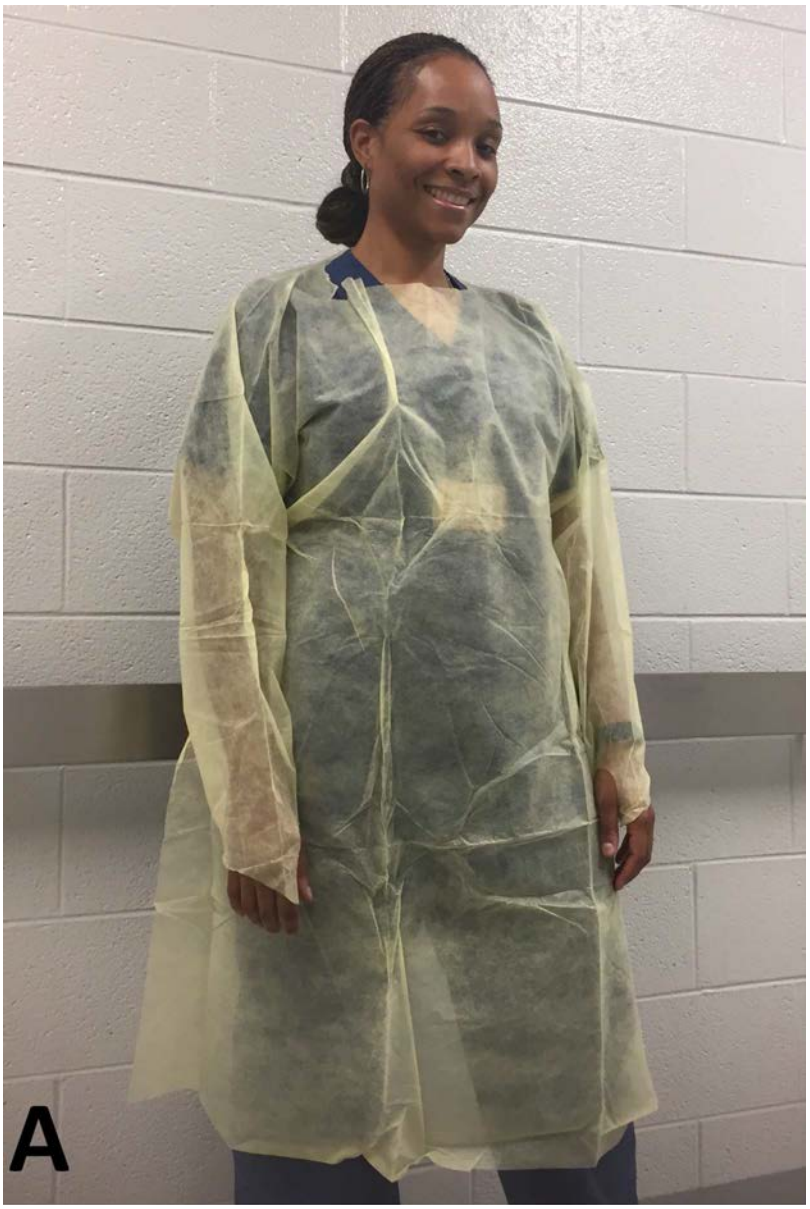

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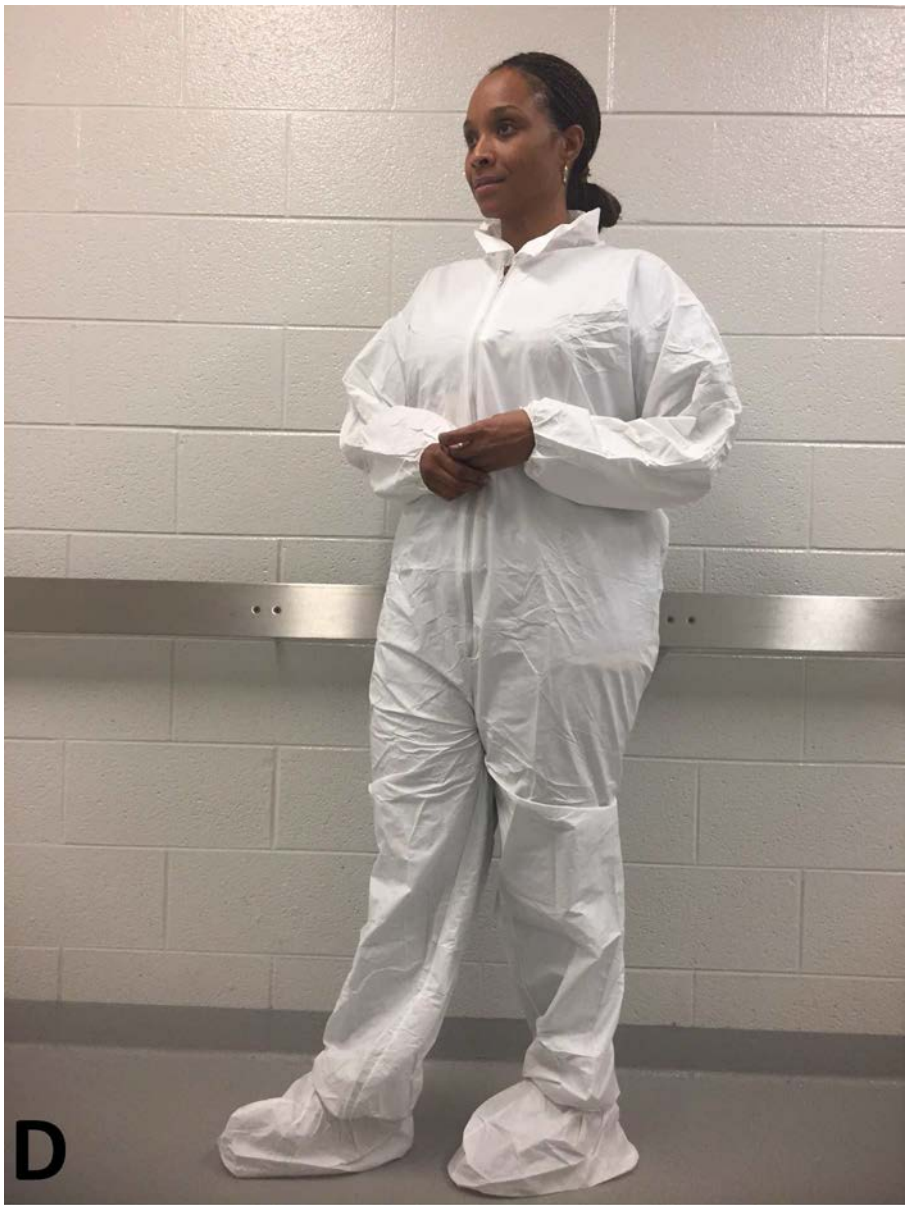
739x1038mm (72 x 72 DPI)

863x1151mm (72 x 72 DPI)



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1108x682mm (72 x 72 DPI)

1041x609mm (72 x 72 DPI)

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