IIJA Compliant Gloves Specifications, Certification Levels, and Attributes

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Overview

The purpose of this document is to identify specifications, certification levels, and attributes of Infrastructure Investment and Jobs Act (IIJA) compliant gloves.

General Requirements

To ensure and sustain an NIH-mission ready supply chain, the below requirements must be met.

I. The Contractor shall ensure continuity and ready availability (to ensure no lapse in delivery and order fulfillment support to NIH) to sustain delivery to the government within 1 week of Task Order placement.

II. When a Contractors' product has changed, as a result of new technology or if the product is no longer available (e.g., discontinued production), the Contractor shall propose a replacement product, of equal or greater capabilities/value. The proposed alternative must be approved by the government COR and Contracting Officer prior to production and/or delivery and incorporated into the contract as a contract modification.

III. The Contractor shall be allowed to replace the product(s) on the Contract twice per year. The new technology shall be approved by the Government COR and Contracting Officer. Under no circumstances shall NIH incur additional costs for product upgrades, unless the cost variance is approved by the government COR and government Contracting Officer and incorporated via formal contract modification. Upon approval of a product upgrade, the Contractor shall retain resources necessary to address all Task Order requirements for the legacy product(s). If resources are not available to address all requirements for the legacy product(s), the legacy product(s) shall be replaced with the Contractors' new product to meet the requirements of the existing Order, at no additional cost to the Government.

IV. The Contractor shall have:

    i. Capability for nationwide delivery (validated through previous commercial or government contracts)

    ii. Ability to deliver to NIH Supply Center up to twice weekly on designated day and to designated dock

    iii. Surge capability to meet the disaster relief or increased customer demands (ex. Force majeure events, evolving customer needs, etc.)

PPE Gloves

The below table lists the expected utilization of latex, nitrile, vinyl, neoprene and polyisoprene gloves and associated certifications.

Table 1. Utilization of gloves and associated certifications

PPE Glove Type	Proposed Utilization (Estimates)	Certification Level
Latex	15%	ASTM D3577[1], ASTM D3578[2], ASTM D5151[3], ASTM D6124[4], ASTM D6978[5], ASTM F2878[6], ASTM F1671[7], FDA CFR 21 177.2600 [8], ISO 11193[9], NFPA 1999[10], USP 800[11], ANSI/ISEA 105-2011[12]
Nitrile	75%	ASTM D5151, ASTM D6124, ASTM D6319[13], ASTM D6978, ASTM F2878, ASTM F1671, NFPA 1999, USP 800, ISO 11193, ANSI AQL of 1.5, ANSI/ISEA 105-2011
Vinyl	5%	ASTM D5151, ASTM D5250[14], ANSI/ISEA 105-2011
Neoprene (polychloroprene), Polyisoprene	5%	ASTM D3577, ASTM D6978, ASTM F1671, ASTM D6977[15], ANSI/ISEA 105-2011

Single-use examination gloves must meet the standards of ASTM D6319 and NFPA 1999.

The below table lists the expected utilizations of latex, nitrile, and vinyl gloves and glove sizes.

[1] ASTM D3577 Standard Specification for Rubber Surgical Gloves
[2] ASTM D3578 Standard Specification for Rubber Examination Gloves
[3] ASTM D5151 Standard Test method for detection of holes in medical gloves
[4] ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves
[5] ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
[6] ASTM F2878 Standard Test Method For Protective Clothing Material Resistance To Hypodermic Needle Puncture
[7] ASTM F1671 Standard Test Method For Resistance Of Materials Used In Protective Clothing To Penetration By Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration As A Test System
[8] FDA CFR 21 177.2600 Rubber articles intended for repeated use
[9] ISO 11193 Single-use medical examination gloves
[10] NFPA 1999 Standard on Protective Clothing for Emergency Medical Services
[11] USP 800 Hazardous Drugs – Handling in Healthcare Settings
[12] ANSI/ISEA 105-2011 - Hand Protection Selection Criteria
[13] ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Application
[14] ASTM D5250 Standard Specification for poly(vinyl chloride) gloves for medical application
[15] ASTM D6977 Standard Specification for Polychloroprene Examination Gloves for Medical Application

Table 2. Expected utilization of gloves and sizes

PPE Glove Size	Proposed Utilization (Estimates)
X-Small	5%
Small	10%
Medium	40%
Large	25%
X-Large	15%
2XL to 6XL	5%

Table 3. Specific Attributes of IIJA Compliant Nitrile Gloves

Protective Attributes and Ratings	Characteristics
• Puncture level 2-4 • Tensile Strength range 14 MPa to 21 MPa • ***Chemical Resistance:*** acid, base, oxidizing, flammability, corrosives • Chemo rated • Clean room rated • ***Required Protection:*** UV light, radiation rated • Cold resistant • Heat resistant • Cut resistance 1-5 • Tear Level 1-4	• Textured & non textured • ***Thickness****:* Fingertips 0.05-0.10 mm and 2.8-9.1 mil; Palm 3.9-4.7mil • Length 8-12 inches • Cuffed (beaded, extended) and non-cuffed • Exam, medical grade for patient care, surgical, laboratory (bioresearch), dental, animal handling • Latex free • Range of colors to include blue, purple, black, white • Ambidextrous and hand specific options • Non-Sterile & Sterile

When providing PPE commodity lists to the government, contractors must include the American National Standards Institute (ANSI) Acceptable Quality Levels (AQLs) for all gloves including nitrile gloves. The AQL refers to an internationally used quality standard for measuring the % of pinhole defects in disposable gloves. The lower the AQL, the lower the risk of exposure.

ALL PPE RESPONSES SHOULD INDICATE WHICH LEVEL OF PROTECTION IS PROVIDED BY THE RESPONSIVE OFFEROR:

Table 4. Civilian PPE

OSHA/EPA Classification [16][17]	Level A	Level B	Level C	Level D
Protections Provided	Highest level of skin, eye, respiratory protection	Highest level of respiratory protection; lower level of skin protection.	Lower level of respiratory and skin protection. Adequate for radiation event response where other hazards have been determined not to be present	Lowest level of respiratory and skin protection.
Indications	Identified or suspected hazards requiring maximal skin, eye, and respiratory protection. Working in confined areas where hazards have not been fully characterized.	Identified or suspected hazards requiring maximal respiratory protection. Working in atmospheres containing less than 19.5% oxygen. Lower-level skin hazard may be present.	Hazard have been identified. Hazards will not be absorbed by or adversely affect exposed skin. All criteria for using an air purifying respirator are met (i.e., concentrations of all airborne contaminants are known, appropriate filters are available, oxygen levels are sufficient).	Atmosphere contains no known hazards. No or very low potential for unexpected respiratory or skin contact with environmental hazards.
Who Should Wear	First responders When identified or potential risk of biological, liquid vapor chemical	First responders When entering the most heavily contaminated radiation zones to rescue victims or	First responders and first receivers When caring for patients/victims likely to be contaminated with	First receivers When working in post-decontamination areas should wear Standard

[16] OSHA PPE information
[17] EPA PPE information

OSHA/EPA Classification [1617]	Level A	Level B	Level C	Level D
	hazard exposure exists	protect valuable property necessary for public welfare.	radiological material.	Precautions PPE (per protocol) for infection control purposes[18]

[18] Standard precautions PPE and procedures used to prevent transmission of infections within healthcare settings provides adequate protection against low levels of radiological contamination that may be found in post-decontamination areas of the hospital (e.g., emergency department and surgical suites). No formal PPE is required to be worn when delivering care to persons with high dose radiation exposure although reverse isolation procedures will need to be observed as neutropenia becomes prominent.