Document Summary

Detail Type	Detail
Event ID	0000016701
Commodity	Masks, Respirator and Surgical
Attachment (Exhibit)	Exhibit 2
Addendum	-
Group-Class	6532 - Medical/Dental/Veterinary Equip./Supplies
Bid Specification	6532-5278
Revision Level	1
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Revision History

Bid Spec	Rev Level	Revision Date	Author	Summary of Changes
6532-5278	I.R.	May 18, 2020	Wriston, M.	Initial release
6532-5278	1	June 3, 2020	Wriston, M.	Added shelf life and labeling requirements.

1.0 SCOPE

This specification describes the minimum requirements for surgical masks and N95 respirators that will be used by the State of California to protect the State from the COVID-19 pandemic.

2.0 APPLICABLE LAWS and INDUSTRY STANDARDS

Specifications, standards and codes referenced in this document in effect at the time of the Request for Information (RFI), Request for Proposal (RFP), or Invitation for Bid (IFB) form a part of this specification.

- Centers for Disease Control and Prevention (CDC)
- Occupational Safety and Health Administration (OSHA)
- National Institute for Occupational Safety and Health (NIOSH)
- National Personal Protective Technology Laboratory (NPPTL)
- U.S. Food and Drug Administration (FDA)
- ASTM International

3.0 TECHNICAL REQUIREMENTS

3.1 Shelf Life

All surgical masks and N95 respirators shall have a shelf life of at least 2 years at the time of manufacturing and at least 18 months left on the shelf life upon delivery to the State. All masks and N95 respirators (or the packaging) shall be clearly labeled with one of the following:

- Manufacturing date and shelf life
- Manufacturing date and expiration date

3.2 Disposable N95 Respirator

All N95 particulate respirators shall be NIOSH approved and designed to provide respiratory protection of at least 95 percent filtration efficiency against airborne particles but is not resistant to oil. All N95 respirators shall have the NIOSH Testing and Certification approval number, e.g., TC-84A-XXXX provided to the State of California for validation during the procurement process.

3.2.1 Vented

Vented N95 respirators incorporate an exhalation valve that is designed to release hot, humid exhaled breath, helping to reduce heat build-up and moisture inside the facepiece. The vent is a one-way valve that allows your breath to exit without condensing on the inside of the mask or fogging up eyeglasses. N95 respirators with exhalation valves should not be used when sterile conditions are needed.

3.2.2 Non-Vented

Non-Vented N95 respirators do not contain a one-way valve but provide protection to both the wearer as well as people in close proximity of the wearer because both inhalation and exhalation are filtered.

3.2.3 Surgical N95

Surgical N95 respirators are also known as medical respirators or healthcare respirators that in addition to NIOSH approval must also be listed by the FDA for use by healthcare professionals during surgery and other medical tasks, to help prevent contamination.

3.3 Surgical Masks

A surgical mask covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials and must be cleared by the U.S. Food and Drug Administration (FDA). Masks must be classified by the FDA as either:

- FXX - Mask, Surgical or
- QKR - Face Mask (Except N95 Respirator)

3.3.1 ASTM F2100 Levels

All surgical masks shall meet the requirements of ASTM F2100 - Standard Specification For Performance Of Materials Used In Medical Face Masks. The level of protection for each mask is listed below.

3.3.1.1 Level 1: Face masks often feature ear loops and are the general standard for both surgical and procedural applications. They're meant for low-risk situations where there will be no fluid, spray, or aerosol.

3.3.1.2 Level 2: Face masks provide a barrier against light or moderate aerosol, fluid, and spray.

3.3.1.3 Level 3: Face masks are for heavy possible exposure to aerosol, fluid and spray.

Table 1: ASTM F2100 Levels

Requirement	**Level 1**	**Level 2**	**Level 3**
Fluid Resistance	80 mmHG	120 mmHG	160 mmHG
Bacterial Filtration Efficiency (BFE)	95% (minimum)	98% (minimum)	98% (minimum)
Particulate Filtration Efficiency (PFE) @ 0.1 micron	95% (minimum)	98% (minimum)	98% (minimum)