PROCUREMENT DEPARTMENT
Rm 120 Municipal Services Building
Philadelphia, PA 19102-1685
FAX: (215) 686-4716

CITY OF PHILADELPHIA

Mary E. Stitt
Procurement Commissioner

June 8, 2015

BID NUMBER: S5Z61430

TITLE: Accelerator Gloves

DEPARTMENT: VARIOUS

DATE TO OPEN: June 22, 2015 at 10:30 AM

ADDENDUM # 1

TO ALL BIDDERS:
You are hereby notified of the following changes to the above mentioned bid:

Attached are the formal Procurement Specifications for the subject bid.

Please sign, date and return this addendum with your bid to the Procurement Department, 1401 J.F.K Boulevard, Bid Room 170A, Philadelphia, PA 19102-1685 as it now becomes a part of the proposal.

T. Vinson, Buyer

AUTHORIZED SIGNATURE

FIRM NAME (PRINT)

DATE

TV/dr

CITY OF PHILADELPHIA
PROCUREMENT DEPARTMENT
STANDARDS DIVISION

SPECIFICATION

ACCELERATOR FREE NITRILE EMERGENCY MEDICAL GLOVES

TECHNICAL SPECIFICATIONS FOR NITRILE GLOVES

1. SCOPE

1.1 Purchase of various accelerator free nitrile hi risk gloves for use primarily in medical applications city wide.

2. DEFINITION

2.1 **ASTM** – American Society for Testing and Materials

2.2 **Batch** – A quantity of gloves produced from a single, incoming shipment of incoming raw material – subset of a lot. Batch sizes must be traceable to production line, operators, packaging and the polymer coat process.

2.3 **Batch Number** – A unique number assigned to all gloves produced from a single batch used in tracking materials through the production process and in tracing quality problems to their source.

2.4 **Date of Manufacture** – A distinct and separate number that clearly identifies the date of manufacture – not the lot number – cannot be coded.

2.5 **Lot** – A quantity of gloves produced in a given time period based on a formula or recipe.

2.6 **Lot Number** – Unique number assigned to specific dates of production and utilized to trace quality problems to their source.

2.7 **Manufacturer** - A factory that operates the production line and controls the quality of the end product.

2.8 **Package** – The wrapping or enclosure directly containing the smallest number of gloves from which the user withdraws product for use, commonly referred to as a box.

2.9 **Private Labeler** - The entity that procures product from a manufacturer and whose name appears on the product labeling.

2.10 **Shall** – This term indicates a mandatory requirement.

2.11 **Standard** – The established requirements of NFPA 1999–2013 edition, ASTM D3578 or other standards as referenced and set forth in this document.

2.12 **Independent Third Party Test Laboratory** – Third Party is identified as a nationally recognized test laboratory (NRTL) independent of the factory, importer, private labeler, or distributor, and having no interest, partnership, funding from or to, or located on the premises of

and must be ISO 17025 third party accredited and have the appropriate scope of accreditation for the test being performed.

2.13 **Will** – This term indicates a mandatory requirement.

3. CERTIFICATIONS & SPECIFICATIONS

3.1 BIDDERS MUST MEET ALL CERTIFICATIONS AND SPECIFICATIONS CONTAINED IN THIS DOCUMENT. IF A BIDDER DOES NOT MEET A CERTIFICATION OR SPECIFICATION LISTED, THEY WILL BE DECLARED NON-RESPONSIVE. SEE ATTACHED SPECIFICATION WORKSHEET.

3.2 NFPA 1999-2013

3.3 ISO 9001-2008

3.4 FDA 510K Registration

3.5 **Packaging**

3.5.1 Each box of 100 gloves, (of bid samples and on each post bid shipment) must be marked with a lot #, separate batch #, separate un-coded date of manufacture, model # and design, and glove size in package. No labels or stickers will be accepted.

3.5.2 Each box will have printed legibly the shelf life warranty and recommended storage conditions in accordance with NFPA 1999-2013 requirements.

3.5.3 All gloves (of bid samples and on each post bid shipment) must be in the original manufacturer's packaging. This packaging must not be tampered with. No area should be cut out or covered over by labels other than those put on by the manufacturer.

3.6 **Shelf Life**

3.6.1 The City will not accept any product that has a manufacturing date older than twenty-four (24) months from the date of manufacture.

4. DOCUMENTATION REQUIRED (All Technical Data Packages must include the following):

4.1 ALL REQUIRED DOCUMENTATION MUST BE PROVIDED AT THE TIME OF BID SUBMISSION. THE OMISSION OF ANY REQUIRED DOCUMENTATION OR SAMPLES WILL RESULT IN THE BIDDER BEING DECLARED NON-RESPONSIVE.

4.2 NFPA 1999-2013 Certification by Underwriters Laboratories or Safety Equipment Laboratories.

4.3 ISO 9001-2008 Certification for both manufacturer and private labeler.

4.4 FDA 510K Registration for manufacturer product submitted, including process and color.

4.5 ASTM D3578 Independent 3rd Party Laboratory Test Report showing gloves meet the following criteria as listed below and in the Invitation and Bid document.

4.5.1 Lot Control

4.5.1.1 Each test data must be for a lot < 900,000 gloves.
4.5.1.2 Manufacturer lot and batch traceability key

4.5.2 Chemical Exclusions

4.5.2.1 Chemicals tested less than below detectable levels for all chemicals referenced in Specification Worksheet.
4.5.2.2 Manufacturer letter confirming gloves are NOT manufactured using a chlorinated process.
4.5.2.3 Manufacturer flow chart outlining double polymer coating / non chlorination process.

4.5.3 Physical Requirements

4.5.3.1 Data must clearly show that all physical and dimensions requirements, including tensile, elongation, length, thickness, box count and watertight AQL have been achieved.

4.5.3.2 Data Sets Required to Verify Physical Requirements are Adhered to:

4.5.3.2.1 12" 7.0 Mil Hi Risk Nitrile – 1 Set

4.6 Literature Sheets

Bidders must submit literature sheets that declare minimum tolerances for thickness properties. Average thickness dimensions will not be allowed unless literature sheet declares +/- tolerances. If either minimum or average thickness is not declared, vendor will be deemed non-responsive and will be immediately disqualified. Literature sheets must not be altered.

4.7 Factory invoices must be submitted for the same lots provided for test data in Section 4.5.3.2. Bidders must show that factory submitted was under UL audit during the invoice period to show adherence to NFPA regulations.

5. SAMPLES

5.1 Bidder must submit for evaluation a minimum of 1 box of each size for each glove model considered for bid. All sample gloves must be submitted with all required documentation upon bid submission. Third Party Testing must be submitted as per Invitation and Bid. Failure to submit samples will result in bidder being declared non-responsive.

6. EVALUATION

6.1 Gloves submitted must meet the following criteria:

6.1.1 Less than 5% breakage while routinely trying on the gloves.

6.1.2 Gloves will be field tested to assure that the sizes conform to the needs of fire and various city department personnel.

6.1.3 Gloves shall provide maximum sensitivity so that the user can perform such medical tasks as feeling a pulse, intubation, and picking up small objects in the course of treating a patient. Gloves shall provide a secure grip of smooth, hard objects that are handled by field providers during patient treatment.

6.1.4 Gloves will provide non adherence properties when used in conjunction with veniguards, EKG electrodes and/or medical tape.

7. QUALITY ASSURANCE

7.1 Testing as specified by this standard in section 4.5 shall be conducted on a pre-shipment lot to lot basis. Test data shall be supplied for each shipment of gloves received by the City, upon request for pre-shipment approval. This test data shall be used to verify that:

7.1.1 All gloves received by the city are compliant with this standard

7.1.2 The manufacturer or private labeler maintains NFPA 1999-2013 Edition Certification

7.1.3 No gloves are received for non-certified manufacturer's or factories

7.1.4 Gloves received are not "seconds" or otherwise substandard

8. WARRANTY

8.1 All products are to be warranted against all defects in parts or workmanship. The vendor shall replace any and all products which are found to be defective or substandard.

8.2 The City Procurement Department shall be notified immediately in the event of any of the following:

8.2.1 Problems regarding Good Manufacturing Practices in the production of the product

8.2.2 Any and all problems with compliance to this standard

8.2.3 Any changes affecting the form, fit or function of the product

8.2.4 Any and all recalls of the product.

8.2.5 Any gloves in possession of the City identified by lot and/or batch number as recalled will be replaced at no cost to the City.

9. INDIVIDUAL ACCELERATOR FREE NITRILE GLOVE SPECIFICATIONS

9.1 12" 7.0 Mil Hi Risk Nitrile

- 100% Nitrile / Acrylonitrile Butadiene Rubber / White Color
- Glove Surface – Finger Tip Texture / RezTak No Stick Surface
- 12" Minimum Length
  - Minimum Thickness 7.0 Mil / 4.7 Mil Palm / 3.3 Mil Cuff

- Sizes Available S – 3XL
- Palm Width +5mm Tolerance
  - S – 85 / M – 95 / L – 105 / XL – 110 / 2XL – 118 / 3XL – 126
- Watertight AQL 0.65
- Tensile Before Aging 23 / After Aging 28
- Elongation Before Aging 650 / After Aging 700
- Process Properties:
  - Double Polymer Coated
  - Non-Chlorinated
  - Powder free
- Chemical Exclusions (Must not be used in the manufacturing process)
  - All Accelerators
  - Mercaptobenzothiazole (MBT)
  - Tetramethylthiuram disulfide (TMTD)
  - Butylhydroxyanisole (BHA)
  - Chlorine
  - Sulfur
  - Thiurams
  - Carbamates
  - Zinc
  - Zinc dibutylthiocarbamate (ZDBC)
  - Zinc diethylthiocarbamate (ZDEC)
- Lot Control < 900,000 gloves
- Batch Control < 40,000
- Sampling Plan ANSI / ASQ Z1.4-2008
- Packaging 100 Box / 10 Box Case