LANDSCAPE FOR SAFE INJECTION, PHLEBOTOMY, AND WASTE MANAGEMENT EQUIPMENT

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Standards, Specifications, and Products

Making Medical Injections Safer Project

This report contains an assessment of the current market availability of safe injection, phlebotomy, and waste management equipment as well as guidance on the procurement of equipment by PATH, a subcontractor to the Making Medical Injections Safer Project. This report was prepared under the auspices of the subagreement IS-002-09 modification between PATH and JSI for the Making Medical Injections Safer Project under JSI's Cooperative Agreement 5U62PS124534-05.

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Table of Contents

Safe Injection

Injections are one of the most common health care procedures. In developing and transitional countries at least 16 billion injections are administered each year. The majority—around 95 percent—are given in curative care, 3 percent in immunization, and the final 2 percent for other services including blood transfusions and contraception. In certain regions of the world the use of injections have far overtaken the need—an estimated 70 percent of injections have been determined unnecessary or available in the form of oral administration.[1] A recent study indicates that each year unsafe injections cause an estimated 1.3 million premature deaths, a loss of 26 million years of life, and an annual burden of US$535 million in direct medical costs.[2]

According to the World Health Organization (WHO), a safe injection is one that does not harm the recipient, does not expose the provider to any avoidable risks, and does not result in any waste that is dangerous for the community. Best infection control practices as recommended by WHO are as follows:

- The use of sterile, single-use injection devices, syringes with reuse-prevention features, and syringes with needlestick-prevention features (e.g., safety syringes) for general purposes.
- The safe collection and disposal of used sharps (e.g., needles, syringes with fixed needles) at the point of use and their safe and environmentally responsible disposal to protect the health care worker and general public from needlestick injuries.
- The provision of matching quantities of single-use injection devices, appropriate diluents, and safety boxes with all injectable medicines.
- The prevention of injection overuse. National drug policies should promote the rational use of therapeutic injections.

Industry Landscape of Safe Injection Equipment

An industry landscape of the current market availability of curative safe injection equipment was conducted in 2008 and updated in 2009. The results of this landscape can be found in Attachments A–I. Products included in the curative safe injection commodities landscape include reuse prevention syringes, reuse prevention with needlestick-prevention syringes, insulin syringes, and safety boxes. Only manufacturers that are WHO prequalified, International Organization for Standardization (ISO) certified, and/or hold certifications from a stringent regulatory authority are included in Attachments A–I. This list should not be considered an endorsement of any particular product or vendor. It should be noted that there are many high-quality products for each of these categories, and only a small sample has been included in this landscape.

Information on products and manufacturers was collected from the following sources:

- WHO list of prequalified therapeutic (curative) devices and waste management products.
- Products and manufacturers identified during the 2008 tender process for the Presidents Emergency Plan for AIDS Relief-funded Making Medical Injections Safer project.

[1] World Health Organization (WHO). *Injection Safety Fact Sheet N.231*. WHO. Geneva: WHO; 2006.

[2] Miller M, Pisani E. The cost of unsafe injections. *Bulletin of the World Health Organization*. 1999; 77(10); 808–811.

- Primary online research: The International Sharps Injury Prevention Society (ISIPS), www.isips.org and University of Virginia Health System, http://www.healthsystem.virginia.edu/internet/EPINet/safetydevice.cfm#1.

Companies were queried for information on available products, certifications, price, and country of origin. The pricing information provided in the attachments is a range. Actual prices will vary depending on the quantity, product specifications, and date of purchase. For current information on products listed in this summary, including pricing, it is suggested that manufacturers be contacted at the time of order. The product information is included in the following attachments:

Attachment A—Syringes With Reuse Prevention Features (autodisable)
Attachment B—Syringes with Needlestick Prevention Features
Attachment C—Insulin Syringes
Attachment D—Cardboard Safety Boxes and Sharps Containers

Quality

Quality is the most important selection criterion when choosing injection and phlebotomy equipment. It is highly recommended by international agencies (e.g., WHO, United Nations Children's Fund (UNICEF), United Nations Population Fund (UNFPA)) and the World Bank that institutions procuring injection equipment develop a list of manufacturers that are prequalified on the basis of certain criteria which include international quality standards.

Standards

Safety, quality, and product standards published by international or national regulatory authorities or standards bodies establish the minimum quality for products that are made, imported, or sold within a particular country or region. Product standards only address the safety and performance of the product produced; design features that are a matter of choice or discretion are not normally included in a standard.

Selecting a good quality product begins with determining if the product has been prequalified by WHO or meets the applicable standards set forth by the ISO. In addition to these international standards there are also internationally recognized domestic market clearances that would indicate a quality product. The internationally recognized domestic market clearances are those given by the five founding members of the Global Harmonization Task Force (GHTF)—Australia, Canada, European Union, Japan, and the United States. A product which is licensed in any of these five countries signifies a quality product.

WHO Prequalified Products

Since 1979, WHO, in collaboration with the UNICEF Supply Division, has developed and maintained a series of performance specifications and test procedures for injection devices. Although this program began with immunization commodities, over the past few years a new approach based upon three key criteria—Performance, Quality, and Safety (PQS)—has been developed and maintained, and now includes therapeutic devices and waste management products. Products must have performance characteristics that meet the relevant specification, quality, and reliability standards that are appropriate for field conditions. They must also meet safety standards to ensure no harm is caused to users, patients, or to the environment over the course of the product's life cycle.

One of the key aims of the PQS is to bring WHO and UNICEF into a more productive relationship with users, key partners, and industry. The intention is to create a product development, improvement, and innovation cycle composed of the following three steps:

1. Establish and/or adopt international standards to provide a framework of reference for the design, development, and production of each product.
2. Develop and maintain technical specifications and related test procedures that adequately reflect programmatic and operational needs for each type of product.
3. Monitor products post-market in order to assess performance, quality, and safety characteristics over the product lifecycle from the perspective of the user; monitor product suitability for programmatic and operational needs.[3]

WHO's prequalification is for a specific product and is not an overall approval of the manufacturer or product line. Therefore when reviewing prequalified products on the WHO PQS website it is important to note the manufacturer, product type, brand name, and size of the syringe/safety box. WHO prequalifies therapeutic syringes by requiring they meet the ISO 7886-4 standard. Additionally, WHO requires the product be licensed in one of the GHTF countries. For waste management devices such as safety boxes there is no ISO product standard. WHO has developed their own performance specification for safety boxes, WHO/PQS/E10/SB01.1, as guidance for the approval of a good-quality product. Some of the requirements outlined in the performance specification relate to performance, environmental impact, physical characteristics, and material use. WHO ensures that an approved safety box manufacturer adheres to these performance specifications before prequalifying their product.

As new products and manufacturers continue to emerge, updated information on WHO prequalified therapeutic devices can be found on the following WHO webpage: http://www.who.int/immunization_standards/vaccine_quality/pqs_prequalified_devices_e13/en/.

For updated WHO prequalified waste management devices, refer to: http://www.who.int/immunization_standards/vaccine_quality/pqs_prequalified_devices_e10/en/index.html

International Organization for Standardization

If a product falls outside of the scope of work of WHO, then the principle international standards authority is the ISO. The ISO is a worldwide federation of national standards bodies responsible for drafting international standards based on the best available evidence and practice.

ISO product standards listed in Table 1 describe the current international standards governing single-use injection equipment.

Table 1: ISO product standards for immunization, curative, and insulin syringes

ISO 7886-3	Sterile hypodermic syringes for single use—Part 3: Autodisable syringes for fixed-dose immunization
ISO 7886-4	Sterile hypodermic syringes for single use—Part 4: Syringes for manual use with reuse-prevention feature
ISO 8537	Sterile single-use syringes, with or without needle, for insulin

[3] Performance, Quality, and Safety (PQS) system page. World Health Organization (WHO) Website. Available at: http://www.who.int/immunization_safety/safe_injections/update/en/index3.html. Accessed September 16, 2009.

Safe injection syringes for immunization are classified under ISO 7886-3. Immunization syringes are not covered in the landscape, but the ISO data is provided as a reference. Safe injection syringes for curative services are classified under ISO 7886-4. Standard disposable insulin syringes are classified under ISO 8537. There are currently no ISO standards for safety boxes.

In Annex 1 there are further details on ISO product standards. To purchase any of the standards, refer to the ISO website at www.iso.org. Beyond the ISO, various international and national standards organizations exist that have established standards to cover a region or country.

Global Harmonization Task Force

The GHTF was established in 1992 in an effort to respond to the growing need for international harmonization in the regulation of medical devices. The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness, performance, and quality of medical devices; promoting technological innovation; and facilitating international trade. The regulatory authorities in each of these countries are internationally recognized. Products which have received a license from any of these GHTF countries are considered a quality product. The market permit provided by each of these countries can be found in Table 2 below.

Table 2: GHTF market permits

GHTF Country	Australia	Canada	European Union	Japan	United States
Market Permit	Australian Register of Therapeutic Goods (ARTG) or European Conformance (CE) mark	Device license	CE mark	Device license	510K device letter

When requesting a quote from a manufacturer, the purchaser should ask if the product has a market permit from any of the GHTF founding members. This can signify a good-quality product if it is neither prequalified by WHO nor has a governing ISO product standard.

Quality Standards

Quality standards are defined as the organizational structure, responsibilities, procedures, processes, and resources needed to implement quality management. Quality standards apply to the manufacturing facility and not to the specific product. The quality standards used by the five founding members of GHTF are listed in Table 3.

Table 3: Quality standards of the five founding members of the GHTF

Founding members	Quality standards
Australia	ISO 13485, ISO 13488
Canada	ISO 13485, ISO 13488
European Union	ISO 13485, ISO 13488
Japan	Current Good Manufacturing Practices (cGMP)

Founding members	Quality standards
United States	Quality System (21 CFR part 820)[4]

ISO 13485 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

ISO 13488 is a component of ISO 9002 certification and specifies the quality system requirements for the production and, when relevant, installation and servicing of medical devices.

Current Good Manufacturing Practice (cGMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate for their intended use and as required by the marketing authorization. cGMP refers to the regulations enforced by the United States Food and Drug Administration (USFDA). They provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.

The quality system in the United States ensures that manufacturers establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for USFDA-regulated products (food, drugs, biologics, and devices) are the same as current good manufacturing practices (cGMPs).

Product Specifications

A product specification covers all of the product attributes necessary for the buyer's requirements. Product specifications include the essential general and performance requirements as well as how to verify product quality. Specifications may demand a higher level of quality then a standard.

Specifications on the following safe injection commodities can be found on pages 9-18 of this report: syringes with reuse-prevention features, syringes with needlestick-prevention features, insulin syringes, and safety boxes.

Purchasing Considerations

Quality is the most important selection criterion when purchasing safe injection commodities. A purchaser should determine whether the commodity has WHO prequalification, meets applicable ISO product standards, and/or is licensed in any of the five GHTF countries. After the product standards have been established, the purchaser should develop the desired product specifications and incorporate them into the bidding documents. During the development of the product specifications for the bidding documents it is important to accurately reference the terminology most widely used for safe injection equipment. This is especially important when referring to safe injection syringes for curative services. The term reuse prevention (RUP) for curative syringes is more accurate than referring to the syringes as an autodisable (AD) syringe. The term AD is used for immunization syringes. Additionally the term reuse prevention with needlestick prevention (RUP + NSP) for curative is more accurate than using the term retractable syringes. This is because not all RUP + NSP syringes have a retracting needle feature, therefore stating retractable limits the applicable products.

[4] World Health Organization (WHO). *Procuring Single-use Injection Equipment and Safety Boxes*. Geneva: WHO; 2003.

In terms of curative safety syringes and safety boxes, there are resources available, for example the WHO PQS system, which identify quality products. For insulin syringes there is an ISO standard for standard disposable syringes but not for insulin syringes with reuse prevention. The landscape lists standard disposable and reuse-prevention insulin syringes. Those manufacturers which produce reuse-prevention insulin syringes have done so voluntarily without guidance from an ISO standard.

Another consideration when purchasing syringes is to purchase enough safety boxes to dispose of the syringes. This is often referred to as bundling. The purchaser should inquire with the manufacturer about the syringe capacity for the safety box based on the size of syringes being purchased. For example, a 5 L safety box holds approximately 75 curative-sized syringes (2 ml, 5 ml, 10 ml). This will provide guidance for forecasting the number of safety boxes needed.

A final purchasing consideration is cost. The prices obtained for the landscape are estimates and are intended to provide guidance. It is advised to directly contact the manufacturer regarding current pricing, based on a purchaser's volume. A summary of the estimated cost for each commodity is provided at the bottom of each attachment.

Phlebotomy Equipment

The landscape also addresses phlebotomy equipment with safety features. The specific product categories included are blood collection needles, tube holders, and winged blood collection sets; intravenous insertion equipment and winged infusion sets; capillary blood collection; lancets; and dental syringes. The information on these products was obtained from primary research online, specifically the ISIPS and University of Virginia Health System websites. Companies were also queried for information on available products, certifications, price, and country of origin. The pricing information, where obtained, is a range. Actual prices will vary depending on the quantity, product specifications, and date of purchase. For current information on products listed in this summary, including pricing, it is suggested that manufacturers be contacted at the time of order. The product information is included in the following attachments:

Attachment E—Blood Collection Needles, Tube Holders, and Winged Blood Collection Sets
Attachment F—Intravenous Insertion Equipment and Winged Infusion Sets
Attachment G—Capillary Blood Collection
Attachment H—Lancets
Attachment I—Dental Syringes

Quality is the most important selection criterion when choosing phlebotomy equipment. There are not as many international resources for identifying good-quality phlebotomy equipment with safety features as there are for curative syringes with safety features. WHO has not developed a prequalification system for phlebotomy equipment with safety features, nor are there ISO product standard specifically addressing safety features for phlebotomy equipment. However there are ISO standards for standard phlebotomy equipment, as listed below in Table 4.

Table 4: ISO product standards for phlebotomy equipment

ISO 6710	Single-use containers for venous blood specimen collection
ISO 10555-1	Sterile, single-use intravascular catheters—Part 1: General requirements
ISO 10555-5	Sterile, single-use intravascular catheters—Part 5: Over-needle peripheral catheters

Note: ISO 6710 applies to evacuated and non-evacuated single-use venous blood specimen containers and does not apply to blood collection needles. Further details on ISO product standards can be found in Annex 1.

In the case of phlebotomy equipment with safety features, a purchaser should verify that the product is licensed in a GHTF country to ensure good quality. It should be noted that there are no product specifications developed for phlebotomy equipment with safety features at this time.

Specification Sheet

Syringes with Reuse Prevention Features

1. General description and purpose

Single-use sterile syringes for general curative services with reuse-prevention features.

Note that the term "**syringes with reuse-prevention feature**" is defined by ISO standard 7886-4 and includes automatic disabling syringes (Type 1) and devices with an elective disabling feature (Type 2). Automatic disabling features activate during the course of injection administration, and elective disabling mechanisms require voluntary activation on the part of the health worker. Additional clarification on automatic disabling can be found in ISO 7886-3.

All engineered safety mechanisms shall be fully described in bid submission documents to clearly indicate how the reuse-prevention feature functions.

Note that needles should be mounted to the syringe and should be detachable.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

For general curative services:

- Plastic, 2 or 3 part, translucent material allowing inspection of drug.
- 2 ml or 3 ml x 23 G x 5/8", 23 G x 1", graduations of 0.1 cc or more.
- 5 ml x 21 G x 1.5", 21 G x 5/8", graduations of 0.2 cc or more.
- 10 ml x 19–21 G x 1.5", graduations of 0.5 cc or more

Note: Needle sizes are examples of the most commonly used size. Purchasers should first determine the need in their country and then verify availability with manufacturers.

Graduations should be in black where possible, calibrated as noted above. Blue may be provided as an option, but must contrast with the plastic in a readable manner.

Needles shall conform to ISO 7886-4 standards and will be of high-quality metal and free of burrs and other imperfections.

4. Packaging and labeling requirements

Syringes should be sterile packed in individual blister packs, with peel off "Tyvek" or equivalent backing, with needles attached to the syringe. Packaging will incorporate Tyvek or another appropriately permeable material to ensure proper terminal sterilization.

Primary syringe packaging should include at minimum the following information, which should be conspicuous on the packaging:

a) Name, address, country of origin of the manufacturer (logos are optional).

b) Manufacturers' product reference.

c) Type and description of product with a clear and conspicuous marking that the product has a reuse-prevention feature.

d) Indication of a fixed or detachable needle.

e) Indication of sterility and sterilization method.

f) Lot number.

g) Expiration date in month/year format.

h) Clear indication that the product is not for reuse.

i) CE mark.

j) Clear and conspicuous marking of the size of syringe and needle.

k) Conditions for appropriate storage.

Boxes containing the syringes must be packed into heavy outer shipping cartons suitable for international transit and must be conspicuously labeled with the type, fixed or detachable needles, quantity, sizes, expiration date, lot number, and name of the manufacturer. Boxes should also indicate conditions for appropriate storage.

Shipping cartons should be clearly and conspicuously labeled with the type, fixed or detachable needles, quantity and size of syringes, the expirations date, the lot number(s), and name of the manufacturer. Shipping cartons should also reference conditions for appropriate storage. Shipping carton markings should also reference their weights and dimensions.

5. Requirements for adherence to quality and performance standards

Syringes shall conform to ISO 7886-4 and documentation shall provide evidence of such.

Products will be prequalified by the world WHO PQS system OR have market clearances from founding countries under the GHTF Task Force.

Syringes shall also conform to the following national regulatory standards:
(insert as applicable)

6. Requirements for instructional materials

Instructions for use must be on the box and included within each box in leaflet form; they must be in the English language and may include pictograms. Other languages may be included in addition, but may not substitute for English. There should be a minimum of 5 copies per box.

7. Additional required information

Additional required information should include:

a) Evidence in the form of certificates, licenses or other verifiable documents confirming compliance with currently published ISO 7886-4.

b) Evidence in the form of certificates, licenses or other verifiable documents confirming market approval from a GHTF country and/or prequalification status under the WHO-PQS.

c) The country of origin and the country from which the product will ship.

d) The weight, dimensions, and total quantity of boxes per shipping carton.

Specification Sheet

Syringes with Needlestick Prevention Features

1. General description and purpose

Single-use sterile syringes for general curative services, including a reuse-prevention feature and a needlestick-prevention feature.

Reuse-prevention feature:

Note that the term "**syringes with reuse-prevention feature**" is defined by ISO standard 7886-4 and includes automatic disabling syringes (Type 1) and devices with an elective disabling feature (Type 2). Automatic disabling features activate during the course of injection administration, and elective disabling mechanisms require voluntary activation on the part of the health worker. Additional clarification on automatic disabling can be found in ISO 7886-3.

Also in accordance with ISO 7886-4, the most appropriate reuse prevention feature offering the highest level of reuse prevention is to be considered for each specific intended use.

Needlestick-prevention feature:

Consistent with the above standards, syringes with needlestick-prevention features must meet the standards of the ISO 7886-4 Type 1 noted above, regardless of whether the engineered needlestick-prevention mechanism is integral to the device or supplied as an add-on feature.

The ISO/CD 23908-1 standard for engineered needlestick-prevention mechanisms is under development. This document will be updated to incorporate the final ISO standard for engineered needlestick-protection devices when it has been released.

All bid submissions shall fully describe how the reuse-prevention devices and needlestick features function.

Note: needles should be mounted to the syringe and may be fixed or detachable. Bid submissions should indicate if the needle is fixed or detachable.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

For general curative services:

- Plastic, 2 or 3 part, translucent material, allowing inspection of drug.
- 2 ml or 3 ml x 23 G x 5/8", 23 G x 1", graduations of 0.1 cc or more.
- 5 ml x 21 G x 1.5", 21 G x 5/8", graduations of 0.2 cc or more.

- 10 ml x 19-21 G x 1.5", graduations of 0.5 cc or more.

Note: Needle sizes are examples of the most commonly used size. Purchasers should first determine the need in the country and then verify availability with manufacturers.

Graduations should be in black where possible, calibrated as noted above. Blue may be provided as an option, but must contrast with the plastic in a readable manner.

Needles shall conform to ISO 7886-4 standards, and will be of high-quality metal, and free of burrs and other imperfections.

4. Packaging and labeling requirements

Syringes should be sterile packed in individual blister packs, with peel off "Tyvek" or equivalent backing, with needles attached to the syringe. Packaging will incorporate Tyvek or another appropriately permeable material to ensure proper terminal sterilization.

Primary syringe packaging should include at minimum the following information, and should be conspicuous on the packaging:

a) Name, address, country of origin of the manufacturer (logos are optional).

b) Manufacturers' product reference.

c) Type and description of product with a clear and conspicuous marking that the product has a reuse-prevention feature.

d) Indication of a fixed or detachable needle.

e) Indication of sterility and sterilization method.

f) Lot number.

g) Expiration date in month/year format.

h) Clear indication that the product is not for reuse.

i) CE markings.

j) Clear and conspicuous marking of the size of syringe and needle.

k) Conditions for appropriate storage.

Boxes containing the syringes must be packed into heavy outer shipping cartons suitable for international transit and must be conspicuously labeled with the type, fixed or detachable needles, quantity, sizes, expiration date, lot number, and name of the manufacturer. Boxes should also indicate conditions for appropriate storage. Shipping cartons should be clearly and conspicuously labeled with the type, fixed or detachable needles, quantity and size of syringes, the expirations date, the lot number(s), and name of the manufacturer. Shipping cartons should also reference conditions for appropriate storage. Shipping carton markings should also reference their weights and dimensions.

5. Requirements for adherence to quality and performance standards

Syringes shall conform to the ISO 7886-4 standard, and the proposal shall provide evidence of such.

Products will be prequalified by the WHO PQS system OR have market clearances from founding countries under the GHTF Task Force.

Syringes shall also conform to the following national regulatory standards:
(insert as applicable)

6. Requirements for instructional materials

Instructions for use must be on the box and included within each box in leaflet form; they must be in the English language and may include pictograms. Other languages may be included in addition, but may not substitute for English. There should be a minimum of 5 copies per box.

7. Additional required information

Additional required product information should indicate all standards to which it complies, including a minimum requirement that they meet currently published ISO or other internationally recognized standards as well as:

a) Evidence in the form of certificates, licenses or other verifiable documents confirming compliance with currently published ISO 7883-4.

b) Evidence in the form of certificates, licenses or other verifiable documents confirming market approval from a GHTF country and/or prequalification status under the WHO PQS.

c) The country of origin and the country from which the product will ship.

d) The weight, dimensions, and total quantity of boxes per shipping carton.

Specification Sheet

Single-Use Standard Disposable Insulin Syringe

1. General description and purpose

Needle gauges and lengths are subject to variation based on intended use and are provided as an example.

The scale shall be graduated in units of insulin and shall refer to the strength of insulin. The nominal capacity shall be designated in milliliters.

U-100: Nominal capacity: 1,0/Minimum length of scale: 57 mm/Scale interval: 1.
U-40: Nominal capacity: 1,0/Minimum length of scale: 50 mm/Scale interval: 1.

Product should indicate all standards to which it complies, including a minimum requirement that currently published ISO 8537 or other internationally recognized standards are met

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

Syringe size: 1 ml x 28–30 G x 1/2".

4. Packaging and labeling requirements

Syringes should be sterile and packed in individual blister or ribbon packs with peel off or rigid packaging.

Primary syringe packaging should include at minimum the following information, and should be conspicuous on the packaging:

- Name and logo of manufacturer.
- Manufacturers' product reference.
- Type and description of product.
- Indication of sterility and sterilization method.
- Lot number.
- Expiration date in month/year format.
- CE mark.

5. Requirements for adherence to quality and performance standards

ISO 8537: Sterile single-use syringes, with or without needle, for insulin.

6. Requirements for instructional materials

Instructions for use must be either on the box or included within each box in leaflet form and must be in

the English language and/or nonverbal symbols. Instructions in other languages may be included but may not substitute for English.

7. Additional required information

a) Boxes containing the syringes must be packed into heavy outer shipping cartons suitable for international transit and warehouse management.

b) Shipping cartons should be clearly labeled with the type, quantity, and size of syringes, as well as the name of the manufacturer and the lot number(s).

c) Product should indicate country of origin and the country from which product will ship.

d) Total weights, dimensions, and total quantity of boxes per shipping carton should be indicated.

Specification Sheet

Cardboard Safety Boxes and Other Sharps Containers

1. General description and purpose

Compliant with WHO specifications for syringe disposal boxes.

Boxes must be water resistant, puncture resistant, and suitable for use in the collection of used syringes and needles.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

5L safety box suitable for disposing up to 100 syringes (depending on the syringe size and other conditions). Other safety box sizes: 2.5 L, 10 L, and 15 L; depends on manufacturer.

4. Packaging and labeling requirements

Safety boxes should be flat-packed and palletized, or in another form of containment for air or surface freight.

Product information should include:

- Country of origin and country from which the product will ship.
- Total quantity per box.
- Weight, dimensions, and total quantity of boxes per shipping carton.

Labels should include at minimum the following information, and should be conspicuous on the packaging:

- Name and nature of item.
- Name and logo of manufacturer.
- Instructions for use including pictorials or instructions in English.
- Clear indication of hazards associated with the contents of the safety box.
- Instructions for safe disposal.
- Instructions for assembly.

5. Requirements for adherence to quality and performance standards

ISO 8537: Sterile single-use syringes, with or without needle, for insulin.

6. Additional required information
WHO–PQS E10/SB01.1: Safety box for the disposal of used sharps (performance specification). **Neither WHO nor ISO currently publish standards for safety boxes.*

Personal Protective Equipment

This assessment of the current market availability of personal protective equipment (PPE) provides guidance for ministries of health on the procurement of equipment to improve the safety of waste handlers and incinerator operators at health care facilities. The information regarding manufacturers and distributors was collected during the fourth quarter of 2008. The results of this landscape survey can be found in Attachments J and K. Products included in the survey include protective respirators (dust masks) and protective gloves for incinerator operators. For protective respirators, only National Institute of Occupational Safety and Health (NIOSH)-certified products were included in this report. For protective gloves there are currently no established international or national certification guidelines. This list should not be considered an endorsement of any particular product or vendor. It should be noted that there are other quality respirators and gloves on the market, and only a small sample has been included in this landscape survey.

Information on products and vendors was collected from the following sources:

- Products and manufacturers identified on the respirator and glove specification sheets.
- Primary online research (manufacturer and distributor websites) by PATH staff.

Identified manufacturers were contacted and advised that information was being collected. Manufacturers were queried for information on available products, specifications, distributors, certifications, price, and lead time. They were advised that information provided would be shared with various ministries of health for the purpose of supporting the sustainability of the PPE commodity supply. There was only one manufacturer out of seven that responded to the inquiry. The remaining information was obtained from manufacturer and distributor websites and through telephone calls to the manufacturer or distributor.

All of the manufacturers listed sell through distributors; all of those listed ship internationally. Attachment J lists manufacturers of protective gloves for incinerator operators; Attachment K lists manufacturers of protective respirators (dust masks) for incinerator operators. Information on international vendors of other types of PPE are excluded because these products tend to be easily purchased in local markets.

Because pricing of the equipment found in Attachments J and K is subject to change, the prices quoted in this report should be considered only as a range. Actual prices will vary depending on the quantity and date of purchase. For current information on products listed in this summary, including pricing, it is suggested that the distributor be contacted at the time of order.

Quality

While PPE would benefit from the same level of international quality modeling as syringes, this level of centralized systems for quality standards is not available. For this equipment, it is recommended that countries work with local standards to ensure appropriate and useable PPE for medical waste handling. For some PPE, like respirators, there are national standards which could be modeled to ensure product quality. There are three national-level standards for respirators: Japanese, European, and American. The Japanese and American respirator standards are published on the internet and can be found in Attachment L. The European respirator standard must be purchased. The national standards for protective gloves are from Europe, Australia, and New Zealand, and require purchase. Attachment L does provide an excerpt of the protective glove standards content.

Standards

There are no international standards for PPE. There are various national standards which are applicable to protective respirators and protective gloves. These national standards can still be a useful guide when purchasing PPE.

Respirators are tested and certified in the United States by NIOSH per 42 Code for Regulations (CFR) Part 84. NIOSH certifies three classes of filters: N-, R-, and P-series. The different filter levels are described in Table 5. A respirator used by an incinerator operator should have a P100 or N100 rating by NIOSH. A P100 respirator will protect against any particulates, including oil-based materials. N-series respirators protect against solid and water-based particulates such as nuisance dust.

Table 5: NIOSH standards for respiratory protective devices, 42 CFR Part 84

Filter Efficiency Levels		**95%**	**99%**	**99.97%**
N	For solid particulates and non-aerosols that do not degrade filter performance	N95	N99	N100
R	For solid particulates and degrading oil-based aerosols (use limitations)	R95	R99	R100
P	For solid particulates and degraded oil-based aerosols (no limitations)	P95	P99	P100

For more information regarding NIOSH or to review the 42 CFR Part 84 test requirements in detail refer to the Centers for Disease Control and Prevention website at www.cdc.gov/niosh. Also refer to the NIOSH standards literature in Attachment L.

The European Committee for Standardization (CEN) has European Standards (EN) for respiratory masks. The procedures for testing and certifying air-purifying and particulate respirators in Europe are governed by EN 143:2000, "Respiratory protective devices—Particle filters, requirements, testing, and marking," and a number of other related standards. All of these related standards refer to EN 143:2000 for the certification test method. The certification process and the requirements for quality control testing are described in the *European Union Personal Protective Equipment* guidelines and are applicable to all personal protection equipment. These associated standards apply to various classes of respirators. For example, reusable half masks are governed by EN 405 or EN 140, and filters are governed by EN 141, EN 143, EN 371, or EN 372. For more information regarding CEN or to purchase EN 143, refer to the CEN website at www.cen.eu.

Beyond NIOSH and CEN, there are also Japanese standards for dust masks issued by the Japanese International Center for Occupational Safety and Health (JICOSH). The standards conform to the Industrial Safety and Health Law No. 57 of 1972. These standards for dust masks can be found in Attachment L.

Protective glove standards have been established in Australia, New Zealand, and Europe. The Australian and New Zealand (AS/NZS) glove standards were established by Standards Australia and are based on the equivalent European standard (Table 6).

Table 6: AS/NZS and EN standards for occupational protective gloves

AS/NZS Standard	EN Standard	Title
2161	-	Occupational Protective Gloves
2161.1	-	Occupational Gloves Part 1: Selection, Use, and Maintenance
2161.2	EN 420	Occupational Gloves Part 2: General Requirements
2161.3	EN 388	Occupational Gloves Part 3: Protection Against Mechanical Risks
2161.4	EN 407	Occupational Gloves Part 3: Protection Against Thermal Risks
2161.5	EN 511	Occupational Gloves Part 3: Protection Against Cold
2161.7	EN 1082-1	Occupational Gloves Part 3: Protection Against Cuts and Stabs

In Attachment L, a brief narrative on the following standards within AS/NZS can be found:

- Selection, use, and maintenance
- General requirements
- Protection against mechanical risks

For more information regarding AS/NZS standards or to purchase standards, refer to their website at www.standards.org.au. For more information about the EN standards or to purchase standards, refer to their website at www.cen.eu.

Safety and performance standards published by international or national regulatory authorities or standards bodies establish the minimum quality for products that are made, imported, or sold within a particular country or region. Standards only address the safety and performance of the product produced; design features that are a matter of choice or discretion are not normally included in a standard. Standards also generally specify methods of use when carrying out basic tests for quality verification.

Specifications

A specification covers all of the product attributes necessary for the buyer's requirements. Specifications include the essential general and performance requirements as well as how to verify product quality. Specifications may demand a higher level of quality then a standard. Beginning on page 23 there are specification examples for the following personal protective equipment: protective gloves for incinerator operators, protective respirators for incinerator operators, protective aprons for waste handlers, protective footwear for waste handlers, protective gloves for waste handlers, and medical waste plastic bin liners.

Purchasing Considerations

The protective respirator consists of two main parts—the face mask (half-mask) and two cartridges. The replacement of cartridges for protective respirators should occur approximately every six months, under the assumption that the incinerator operator is using the respirator three to four times a week. All of the face masks have replaceable parts; therefore, a new mask does not need to be purchased when one component is damaged.

Protective respirators come in three sizes: small, medium, and large. The fitting for a protective respirator is important because a good fit seals the user from particulates in the air. It is important to consider the size needed for each user prior to purchasing the mask. When determining the selection of protective respirators prior to procurement, the comfort and preference of the worker should be considered. Ideally, each

incinerator operator should have their own protective respirator. If there are multiple users per respirator, it must be disinfected after each use.

Specification Sheet

Protective Gloves for Incinerator Operators

Managers may use these product specifications to select gloves suitable for incinerator operators to protect their hands against intermittent heat and infectious sharps present while handling biomedical waste during incineration.

1. General description and purpose

To protect operators of small-scale, medical waste incinerators, gloves must protect against heat and be resist to punctures from contaminated sharps. Gloves must be designed to enable the incinerator operator to safely and effectively perform their duties, and must be made of appropriate protective materials.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

1. Resistant to puncture by used injection equipment.
2. Provide protection against contact, convective, or radiant heat.
3. Flame retardant.
4. Will not interfere with dexterity and tactile sensation required for work duties either by design or poor fit.
5. Durable, reusable design without compromised performance.
6. Available in sizes appropriate for all incinerator operators.

4. Candidate materials

For heat protection, gloves can be made of leather and/or insulated with aramid blends, terrycord, or cotton blends (www.gloveassociation.org). Newer, specialized knit materials such as KEVLAR® are available and offer heat protection and puncture resistance. A heavy neoprene design can provide needle resistance; however, this glove design will need a specialized liner to protect against radiant heat.

5. Design specifications

Glove design	Hand-specific, designed for dexterity and comfort in addition to protection.		
Cuff design	Safety cuff design that protects upper wrist but allows for quick glove removal in emergency situations.		
Thickness	Will be material dependant.		
Sizes	Small (7)	Medium (8)	Large (9)
Palm width (mm)	90	102	120
Typical length (mm)	Minimum 127 (5 inches)	Minimum 127 (5 inches)	Minimum 127 (5 inches)

6. Examples of products

http://www.ansellpro.com/main/productSearch3.asp?pid=108
http://www.ansellpro.com/main/productSearch3.asp?pid=125
http://www.perfectfitglove.com/products/product_detail.asp?id=47&catID=1&pseriesid=13
http://www.perfectfitglove.com/products/product_detail.asp?id=23&catID=1&pseriesid=6
http://www.perfectfitglove.com/images/downloads/Perfect%20Fit%20Carbtex%20Brochure.pdf (see heavyweight terry cloth with leather palm and seamless knit with leather palm options).

7. Relevant international standards

(a) AS/NZS 2161: 1998—Occupational Protective Gloves (excluding electrical and medical gloves)

(b) AS/NZS 2161.2—Occupational Protective Gloves: General Requirements

(c) AS/NZS 2161.3-9—Occupational Protective Gloves: Selection for Use Against Mechanical Risks, Thermal Risks (fire and heat), Cold, Hand Knife Cuts and Stabs, Ionizing Radiation, and Radioactive Contamination

(d) The following EN standards apply to occupational gloves:

EN 420	*Occupational Gloves Part 2: General requirements*
EN 388	*Occupational Gloves Part 3: Protection against mechanical risks*
EN 407	*Occupational Gloves Part 3: Protection against thermal risks*
EN 511	*Occupational Gloves Part 3: Protection against cold*
EN 1082-1	*Occupational Gloves Part 3: Protection against cuts and stabs*

Specification Sheet

Protective Respirators (Dust Masks) for Incinerator Operators

Managers may use these product specifications to select respiratory protection for incinerator operators for use during the incineration of medical waste.

1. General description and purpose

To protect incinerator operators against particulates (dust, fiber, fumes, mist, soot, and smoke) generated during incineration. Paper or cloth surgical masks do not protect from hazards inherent in the incineration of infectious medical waste and should not be substituted for an air-purifying respirator (with cartridges).

Respiratory protection is only needed for personnel remaining in the immediate vicinity of the incinerator. Personnel should be properly fitted for an air-purifying respirator, and replacement cartridges must be made available approximately every six months depending on frequency of use.

A protective air-purifying respirator consists of two main parts—a face mask (half-mask) and two cartridges. The mask and cartridges are sold separately. The same brand of mask and cartridges should be purchased for compatibility.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

Face mask:

1. Provides protection against dust, fiber, fumes, mist, soot, and smoke.
2. Is reasonably comfortable when worn under the designated conditions.
3. Fits snugly and does not unduly interfere with the movements of the wearer.
4. Mask material is capable of being disinfected regularly.
5. Strap is either elastic or adjustable.
6. Is made of silicone or thermal plastic polymer (TPE).
7. Is available in a minimum of three sizes: small, medium, and large. Size dimensions will vary by manufacturer and should be requested prior to ordering.

Cartridges:

1. Are able to achieve the National Institute for Occupational Safety and Health P100 or N100 rating, or equivalent European Committee for Standardization certification. P100 cartridges will protect against any particulates, including oil-based materials. N-series cartridges protect against solid and water-based particulates such as nuisance dust.
2. Contain a granular or porous material—such as carbon or coconut—which removes specific air particulates.
3. Are available in bayonet or push-in mounted cartridge or canister form; are able to remove 99.9% of dusts and non-oil-based mists.
4. Enable easy breathing during use.

4. Maintenance guidance

1. Ensure that the cartridges are replaceable and that adequate quantities of spare cartridges are purchased and provided to incinerator operators.
2. Replace filter cartridges approximately every six months (depending on frequency of use) or when breathing becomes difficult; this signifies that the cartridges are full and need to be replaced.
3. Train handlers on the cleaning and maintenance of protective respirators.
4. Each operator should have his or her own respirator; if shared it should be cleaned and disinfected after each use.
5. Ensure the mask fits correctly and all parts are in good working order.
6. A mask must be inspected for damage before use and whenever it is cleaned. Defective respirators must be discarded or repaired by an appropriately trained person.
7. Incinerator operators must store their protective respirators in a place free from dust, sunlight, extreme temperatures, and moisture so that the face mask is not damaged.

5. Candidate materials

Silicone or thermal plastic polymer (TPE) mask with replaceable cartridges.

6. Design specifications

Design	P100 or N100 replaceable dual-cartridge, half-mask respirator.
Cartridge/Canister filter	Bayonet or push-in mounted cartridge or canister form; able to remove 99.9% of dusts and non-oil-based mists.
Heat resistant	Self-extinguishing, heat-resistant materials.
Ventilation	Adequate inhalation and exhalation valve to enable easy breathing.
Fit	Wide sealing flange for a secure seal with special nose bridge.
Visibility	Unobstructed peripheral vision.
Strap	Elastic or adjustable straps for a good fit.

7. Examples of products

http://www.anisafety.com/index.aspx?Command=GroupInfo&GroupID=10580
http://www.moldex.com/pdfs/datasheets/8900_filter.pdf
http://www.msaafrica.co.za/catalog/product502998.html
http://www.gemplers.com/half-mask-respirator
http://www.gemplers.com/product/124374/Premier-Half-mask-Respirator

8. Examples of instructions for use and maintenance guidelines

http://www.moldex.com/pdfs/datasheets/8000seriesinstructionmanual.pdf

9. Relevant international standards

(a) BS EN 143: 2000 Respiratory protective devices – Particle filters, requirements, testing and marking.

(b) *NIOSH-42 CFR Part 84: US Standards for Respiratory Protective Devices.*

(c) *Law No. 57 of 1972: Japanese Standard for Dust Mask to Enforce the Industrial Safety and Health Law. http://www.jniosh.go.jp/icpro/jicosh-old/english/law/DustMask/index.html*

Specification Sheet

Protective Aprons for Waste Handlers

Managers may use these product specifications to select aprons suitable for cleaning staff to achieve protection against biological hazards present during handling and transport of biomedical waste in the clinic setting.

1. General description and purpose

To protect cleaners and other staff who process health care waste from biological hazards that may be present in medical waste. Aprons should be made of materials that are resistant to puncture from contaminated sharps and should be designed to enable staff to safely and effectively perform their duties.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

1. Durable, reusable design that is able to withstand periodic disinfection.
2. Available in at least two sizes appropriate for all cleaning staff in the health facility.
3. Prevent contact with bloodborne pathogens contained in health care waste.
4. Made from puncture-resistant materials to protect against needlestick injuries and cuts from other sharps.

4. Candidate materials

To prevent contact with infective agents and to resist puncture from contaminated sharps, aprons should be made of heavy-duty neoprene, latex, nitrile, or other water-impervious material. Neoprene is desirable. Material should be moisture proof and chemical resistant.

5. Design specifications

Apron design	Cover upper body from waist to neck, lower body from waist to below knees; coupled in back. Apron should have cotton ties and neck loop for easy on/off.
Thickness	Minimum of 0.5 mm. Must demonstrate resistance to puncture from needles and other medical sharps.
Size: (length in inches)	Medium: Approximately 35” x 45” Large: Approximately 35” x 55”

6. Examples of products

http://www.daigger.com/search/searchdisplay?query=aprons&header_search_go.x=3&header_search_go.y=10
http://www.ansellpro.com/main/productSearch2.asp
http://www.professionalequipment.com/default.asp?keyword=aprons

Specification Sheet

Protective Footwear for Incinerator Operators

Managers may use these product specifications to select protective footwear for waste handlers and incinerator operators to protect against uncontained infectious sharps and other hazards during waste handling and incineration.

1. General description and purpose

Waste handlers and incinerator operators should be provided with protective footwear to defend against falling debris, potential bloodborne pathogens, and occupational heat exposure.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

1. Made from cut-resistant materials.
2. Slip-resistant sole.
3. Puncture-resistant sole.
4. Protective against minimal impact.
5. Fit snugly and not unduly interfere with the movements of the wearer.
6. Durable.
7. Capable of being disinfected.
8. Available in sizes to fit all waste handlers (toes should be about 12.5 mm from the front).

*For incinerator operators, boots should be made from heat-resistant materials when available.

4. Candidate materials

Uppers should be made from polyurethane. Soles may be made of polyurethane if a single mold design is used. A vulcanized nitrile rubber sole will resist punctures and heat.

5. Design specifications

Toe impact protection	Toe impact energy up to 90 joules.
Sliding	Sole construction.
Sole puncture protection	Minimum protection of 1200 newtons.
Slip-resistant sole	Deep tread with coefficient of friction >0.5.

6. Examples of products

http://www.idml.com/shop.asp?catid=38&ProdId=279
http://shop.actecs.co.uk/ProductDetails.aspx?productID=709&Categoryid=457
http://www.dickiesstore.co.uk/dickies-workwear/safety-boots-and-footwear/safety-wellington-

boots/FW13105/0/

7. Relevant international standards

(a) CSA Standard CAN/CSA-Z195-M92—Protective Footwear

(b) ANSI Standard Z41-1991—American National Standard for Personal Protection, Protective Footwear

(c) AS/NZS 2210.1—Occupational Protective Footwear, Guide to Selection, Care, and Use

(d) British Safety Institution Standard BS EN 345: 1993—Specification for Safety Footwear for Professional Use

(e) British Safety Institution Standard BS EN 346: 1993—Specification for Protective Footwear for Professional Use

Specification Sheet

Protective Gloves for Waste Handlers

Managers may use these product specifications to select gloves suitable for cleaning staff to achieve protection against biological hazards present during handling and transport of biomedical waste in the clinic setting.

1. General description and purpose

To protect cleaners and other staff who process health care waste from biological hazards that may be present in medical waste. Gloves should be made of materials that are resistant to puncture from contaminated sharps and that are designed to enable staff to safely and effectively perform their duties.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

1. Durable, reusable design that is able to withstand periodic disinfection.
2. Available in sizes appropriate for all cleaning staff in the health facility.
3. Prevent contact with bloodborne pathogens contained in health care waste.
4. Made from puncture-resistant materials to protect against needle sticks and cuts from other sharps.

4. Candidate materials

To prevent contact with infective agents and to resist puncture from contaminated sharps, gloves should be made of heavy weight neoprene, latex, nitrile, or other water-impervious material. Do not use PVC if there is a chance the gloves will be disposed of by burning or incineration.

5. Design specifications

Glove design	Hand-specific, designed for dexterity and comfort in addition to protection. Texture in palm area should provide grip and tactile sensation to enable safety during janitorial activities.		
Cuff design	Straight cuff for maximum protection from contaminated liquids. Cuff should reach at least 75 mm from the upper arm surface when the elbow is flexed at 90°.		
Palm thickness	Minimum of 0.5 mm/20 mil.		
Sizes	Small (7)	Medium (8)	Large (9)
Palm width (mm)	90	102	120
Typical length (mm)	350–370	350–370	350–370

6. Examples of products

http://www.perfectfitglove.com/products/product_detail.asp?id=34&catID=6&pseriesid=10
http://www.perfectfitglove.com/products/product_detail.asp?id=28&catID=6&pseriesid=10
http://www.ansellpro.com/main/productSearch3.asp?pid=90
http://www.ansellpro.com/main/productSearch3.asp?pid=89
http://www.ansellpro.com/main/productSearch2.asp
http://www.ansellpro.com/main/productSearch3.asp?pid=29
http://www.professionalequipment.com/xq/ASP/ProductID.3059/id.8/subID.360/qx/default.htm

7. Relevant international standards

(a) AS/NZS 2161: 1998—Occupational Protective Gloves (excluding electrical and medical gloves)

(b) AS/NZS 2161.2—Occupational Protective Gloves: General Requirements

(c) AS/NZS 2161.10.1-3—Occupational Protective Gloves: Selection for Use with Chemicals and Microorganisms

Specification Sheet

Medical Waste Plastic Bin Liners

Managers may use these specifications to select plastic liners appropriate for safe segregation of infectious, non-sharp health care waste. Special attention will be required to ensure that the plastic liners are manufactured to quality standards outlined in this specification sheet.

These specifications do not apply to plastic autoclave bags.

1. General description and purpose

Regulated medical waste must be properly packaged to ensure effective containment throughout the handling, storage, transport, and treatment processes.

2. Quantity

To be specified by the purchaser.

3. Physical characteristics

1. The bin liners must be leak resistant, impervious to moisture, and tear resistant.
2. The bin liners must be a distinctive red or yellow color, or clear. If a clear bag is used, then the universal biohazard symbol must be appropriately displayed on the bag.
3. The container used to hold regulated medical waste must have either a red or yellow plastic bag plainly visible or, if a clear bag is used, the universal biohazard symbol must be displayed on the container as well as on the bag.
4. Plastic bin liners used for the packaging of medical waste must be managed as regulated medical waste and must not be reused.

4. Candidate materials

Medical waste plastic bin liners must be made of polyethylene. They should be manufactured from low density (LD)/linear low density (LLD) resin, and shall have a density between 0.915 grams/cc and 0.923 grams/cc. Liner material shall be formulated from polyethylene containing metallocene, octane, butane, or hexane-type copolymer resins with a maximum of 15% post-consumer reprocessed polymer. Polyvinyl chloride is not recommended since bags may be burned or incinerated.

Dyes used in the coloration of plastic bin liners will be no greater than 100 ppm of sum incidental concentrations of lead, mercury, hexavalent chromium, and cadmium.

****Autoclave bags or liners must be made of a polypropylene plastic that does not melt at the temperatures achieved during autoclave sterilization (116°C to 135°C).***

5. Design specifications

Minimum thickness (mandatory)	1.50 mil (should be double-bagged if off-site transport is to be performed).
Material density	Low-density (LD) or linear-low-density (LDD) polyethylene.
Bag size	Dimensions will depend on bin size. Must not exceed 44 gallon (38 in x 46 in) to ensure load endurance is not exceeded.
Impact resistance	165 g
Load rating (min.)	35 kg
Tear strength by machine direction and transverse direction methods	480 g
Color and markings	Red or yellow with "Biohazard" or "Infectious Waste" printed in black. Marking should include the universal biohazard symbol. If a clear bag is used, the universal biohazard symbol must be displayed on the container as well as on the bag.
Closure	Twist ties or other restraining devices are required to either be included in each case of liners or otherwise supplied in adequate quantities to cover the amount of liners procured.

6. Examples of products

http://www.heritage-bag.com/products/h_red.asp
http://www.allmed.net/catalog/item/134/2241
http://www.sharpssupply.com/mcart/
http://www.mfasco.com/index.php/infection-control/misc-biosafety-products/cPath/20_405?SID

7. Relevant international standards

(a) *ASTM D2103-86—Standard Specification for Polyethylene Film and Sheeting*

(b) *ASTM D1709-91—Impact Resistance of Polyethylene Film by the Free-Falling Dart Method*

(c) *ASTM D1922-89—Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method*

(d) *State of North Carolina 7240-1P August 18, 2004*

Annex 1

Excerpts from the International Organization for Standards[5] for Injection Devices

Background

The following information has been excerpted from the website of the International Standards Organization (ISO) as of February 27, 2009, to provide a list of references for injection devices. The abstracts and information below do not substitute for the full text of the standard. To purchase and use the standards, please see the ISO website at www.iso.com. Information posted on the ISO website is subject to change at the discretion of the ISO.

It is important to note that not all injection equipment has evolved to include safety features that prevent reuse or needlestick prevention. The abstracts include a definition of the ISO Technical Committee (TC) 84, which is responsible for standards on most injection equipment.

The notable standards for injection safety programs at this time include **7886-3** and **7886-4** for autodisable and reuse-prevention syringes, **ISO/CD 23908-1** under development for sharps protection features, **8537:2007** for insulin syringes, and **7886-1** for standard single-use disposable syringes.

While these standards reference areas where advances have been made to reduce reuse and prevent injuries, it is important to note that these international performance standards can be referenced to procurement of all injection equipment to ensure that quality, sterile, devices are being imported or produced by reputable health product manufacturing companies.

From ISO Technical Committee 84, Devices for administration of medicinal products and intravascular catheters

Scope of TC 84: Standardization of the performance of metered devices and supplies intended for administration of medicinal products, and standardization of syringes, needles, and intravascular catheters.

Excluded:

- Non-catheter devices intended for diagnostic use.
- Anaesthetic and respiratory equipment, including lung ventilators and oxygen therapy devices, covered by ISO/TC 121.
- Cartridge systems for dental use, covered by ISO/TC 106.
- Specific requirements for components and devices, including prefilled syringes, covered by ISO/TC 76.

ISO 7886-3

ISO 7886-3:2005 Sterile hypodermic syringes for single use—Part 3: Auto-disable syringes for fixed-dose immunization

ISO 7886-3:2005 specifies the properties and performance of sterile single-use hypodermic syringes with or without needle, made of plastic materials and stainless steel and intended for the aspiration of vaccines or for

[5] www.iso.org accessed February 27, 2009.

the injection of vaccines immediately after filling. Upon delivering a fixed dose of vaccine the syringe is automatically rendered unusable.

ISO 7886-3:2005 does not specify the design of the auto-disable feature, which is left to the discretion of the manufacturer

ISO 7886-3:2005 is not applicable to syringes for use with insulin (specified in ISO 8537), syringes made of glass (specified in ISO 595), syringes for use with power-driven syringe pumps (specified in ISO 7886-2), auto-disable syringes for variable dose delivery and syringes designed to be prefilled. It does not address compatibility with injection fluids/vaccines.

ISO 7886-4

ISO 7886-4:2006 Sterile hypodermic syringes for single use—Part 4: Syringes with reuse prevention feature

ISO 7886-4:2006 specifies requirements for sterile single-use hypodermic syringes made of plastic materials with or without needle, and intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe can be rendered unusable after use.

ISO 7886-4:2006 is not applicable to syringes made of glass (specified in ISO 595), auto-disable syringes for fixed dose immunization (ISO 7886-3) and syringes designed to be pre-filled. It does not address compatibility with injection fluids. Other standards can be applicable when syringes are used for any other intended purpose than those specified in ISO 7886-4:2006.

NOTE: Syringes designed to reduce the risk of needlestick injuries can also comply with ISO 7886-4:2006 with regard to their reuse prevention properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in ISO 7886-4:2006.

ISO/CD 23908-1

ISO/CD 23908-1 Sharps injury protection—Requirements and test methods—Part 1: Sharps protection features for single-used hypodermic needles, catheters, introducers for catheters and lancing devices

Status: Under development.

ISO 8537:2007

ISO 8537:2007 Sterile single-use syringes, with or without needle, for insulin

ISO 8537:2007 specifies requirements and test methods for sterile syringes, with or without needles, solely for the injection of insulin. The syringes are single-use only, primarily for use in humans. It covers syringes for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100).

Sterile syringes specified in ISO 8537:2007 are intended for use soon after filling as they are not suitable for containing insulin over extended periods of time.

ISO/NP 23907

ISO/NP 23907 Sharps injury protection—Requirements and test methods—Sharps containers

Status: Under development

ISO 7886-1

ISO 7886-1:1993 Sterile hypodermic syringes for single use—Part 1: Syringes for manual use

Specifies requirements (cleanliness, limits for acidity and alkalinity, limits for extractable metals, lubricant, tolerance on graduated capacity, graduated scale, barrel, piston/plunger assembly, nozzle, performance, packaging, labeling) for sterile single-use hypodermic syringes made of plastic materials and intended for the aspiration of fluids or for the injection of fluids immediately after filling. Excludes e.g. syringes for use with insulin, single-use syringes made of glass.

ISO 7886-2

ISO 7886-2:1996 Sterile hypodermic syringes for single use—Part 2: Syringes for use with power-driven syringe pumps

Specifies requirements for sterile single-use hypodermic syringes of nominal capacity 5 ml and above, made of plastics materials and intended for use with power-driven syringe pumps. Does not apply to syringes for use with insulin, single-use syringes made of glass, syringes prefilled with the injection by the manufacturer and syringes supplied with the injection as a doctors kid [sic].

ISO 10555-1:1995

ISO 10555-1:1995; ISO 10555-1:1995/Amd 1:1999; ISO 10555-1:1995/Amd 2:2004 Sterile, single-use intravascular catheters—Part 1: General requirements

Specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application. Does not apply to intravascular catheter accessories, which will be covered by a separate standard.

Related standards to ISO 10555 where abstracts were not available

ISO 10555-2:1996 Sterile, single-use intravascular catheters—Part 2: Angiographic catheters

ISO 10555-3:1996 Sterile, single-use intravascular catheters—Part 3: Central venous catheters

ISO 10555-4:1996 Sterile, single-use intravascular catheters—Part 4: Balloon dilatation catheters

ISO 10555-5:1996 Sterile, single-use intravascular catheters—Part 5: Over-needle peripheral catheters

ISO 11070:1998 Sterile, single-use intravascular catheter introducers

From ISO Technical Committee 76, Transfusion, Infusion, and Injection Equipment for Medical and Pharmaceutical Use

Scope of TC 76: Standardization of transfusion, infusion and injection equipment for medical and pharmaceutical use; terms and definitions for such equipment; specifications for quality and performance of materials and components.

Standardization of containers (such as infusion bottles, injection vials, ampoules, glass cylinders, cartridges, prefillable syringes, etc.) and devices (such as giving sets, blood collecting tubes, etc.) as well as pertinent primary and secondary packaging and functional components (such as elastomeric closures, caps, pipettes and accessories) for medical and pharmaceutical use.

Excluded:

- Performance requirements of metered devices and supplies intended for self-administration of medicinal products, non-prefilled syringes and needles and intravascular catheters, covered by ISO/TC 84.
- Devices intended for respiratory therapy, covered by ISO/TC 121.
- Dental cartridge syringe holder, covered by ISO/TC 106.

ISO 1135-3:1986

ISO 1135-3:1986 Transfusion equipment for medical use—Part 3: Blood-taking set

Specification of requirements for types of sterilized blood-taking sets for single use and for a single donor in order to ensure functional interchangeability of transfusion equipment. The materials and components of the sets are validated by various test methods selected by the manufacturer and, in addition, tests are provided for the release of lots of finished sets.

ISO 1135-4:2004 and ISO/DIS 1135-4

ISO 1135-4:2004 Transfusion equipment for medical use—Part 4: Transfusion sets for single use

ISO 1135-4:2004 specifies requirements for single-use transfusion sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.

ISO 1135-4:2004 also specifies requirements for air-inlet devices for use with rigid containers for blood and blood components.

Secondary aims of ISO 1135-4:2004 are to provide guidance on specifications relating to the quality and performance of materials used in transfusion sets and to present designations for transfusion set components.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over ISO 1135-4:2004.

ISO/DIS 1135-4

ISO/DIS 1135-4 Transfusion equipment for medical use—Part 4: Transfusion sets for single use
Status: Under development

ISO 8536-4:2007

ISO 8536-4:2007 Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed

ISO 8536-4:2007 specifies requirements for single-use, gravity feed infusion sets for medical use in order to ensure their compatibility with containers for infusion solutions and intravenous equipment.

Secondary aims of ISO 8536-4:2007 are to provide guidance on specifications relating to the quality and performance of materials used in infusion sets and to present designations for infusion set components.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over ISO 8536-4:2007.

ISO 8536-5:2004

ISO 8536-5:2004 Infusion equipment for medical use -- Part 5: Burette infusion sets for single use, gravity feed

ISO 8536-5:2004 specifies requirements for types of single-use, gravity feed burette infusion sets of 50 ml, 100 ml and 150 ml nominal capacity for medical use in order to ensure compatibility of use with containers for infusion solutions and intravenous equipment.

ISO 8536-5:2004 also provides guidance on specifications relating to the quality and performance of materials.

In some countries, national pharmacopoeia or other national regulations are legally binding and take precedence over ISO 8536-5:2004.

ISO 8536-8:2004

ISO 8536-8:2004 Infusion equipment for medical use -- Part 8: Infusion equipment for use with pressure infusion apparatus

ISO 8536-8:2004 applies to sterilized infusion sets for single use for use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

ATTACHMENT A
Safe Injection Supplies
Syringes with Reuse-Prevention Features

Manufacturer	Contact Information	Brand Name	Curative Syringe Size	Certifications (WHO PQS, ISO, GHTF)	Country of Origin	Product Information
Abu Dhabi Medical Devices	P.O. Box 30485, Abu Dhabi, United Arab Emirates. Contact: Ms. Anette Rex anette@medeco-uae.com Tel: +97125510111 Fax: +97125511162	MEDECO Inject AD * Not in commercial production as of June 2009.	5ml	WHO PQS E13/30, ISO 7886-4, CE Mark	United Arab of Emirates	http://www.medeco-uae.com/auto.htm
Alshifa Medical Syringes and Manufacturing Co.	1st Industrial City, Dammam P.O. Box 7917, Dammam 31472, Kingdom of Saudi Arabia Contact: Tareq Al-Khateeb alkhateeb@alshifa.com Tel: + 966 3 847 4284 Fax: + 966 3 847 4033	Shifa	3ml	ISO 7886-4, US FDA 510(k)	Saudi Arabia	http://www.alshifa.com/Pages/product.htm
			5ml	ISO 7886-4, US FDA 510(k)	Saudi Arabia	
			10ml	ISO 7886-4, US FDA 510(k)	Saudi Arabia	
Becton Dickinson	1 Becton Drive Franklin Lakes, NJ 07417 Contact: Renuka Gadde Email: Renuka_Gadde@bd.com Tel: 201-847-6480 Fax: 201-847-4845	BD SoloMed™	2ml (2-piece)	WHO PQS E13/11, ISO 7886-4, CE Mark	Spain	http://www.bd.com/products/
			5ml (2-piece)	WHO PQS E13/10, ISO 7886-4, CE Mark		
			10ml (2-piece)	WHO PQS E13/12, ISO 7886-4, CE Mark		
			2ml	WHO PQS E13/21, ISO 7886-4, CE Mark	Brazil	
			5ml	WHO PQS E13/22, ISO 7886-4, CE Mark		
		BD SoloShot VX-2	5ml (2-piece)	WHO PQS E13/17, ISO 7886-4, CE Mark	Spain	http://www.who.int/immunization_standards/vaccine_quality/bd_e13_17.pdf
Hindustan Syringes & Medical Devices, Ltd.	174, Sector 25 Ballabgarh, India 121004 Contact: Rajiv Nath hmdhealthcare@vsnl.com Tel: 91-11-23314785 Fax: 91-11-23313569	KOJAK	2/3ml	WHO PQS E13/01, ISO 7886-4	India	http://www.hmdhealthcare.com/usa/kojak_spe.htm?referringurl=http%3A//www.hmdhealthcare.com/usa/dn.htm
			5ml	WHO PQS E13/18, ISO 7886-4		
			10ml	WHO PQS E13/20, ISO 7886-4		

ATTACHMENT A
Safe Injection Supplies
Syringes with Reuse-Prevention Features

Manufacturer	Contact Information	Brand Name	Curative Syringe Size	Certifications (WHO PQS, ISO, GHTF)	Country of Origin	Product Information
MoniMedi Korea Co., Ltd	#439 -14, Gakyo-ri, Songak-myun Dangjin-gun Chungcheongnam-do Korea Contact: Rudy Mah marketing@monomedikorea.com Tel: 82 - 41 - 3567460 Fax: 82 - 41 - 3567463 US contact: Ken Ulerick nanken@comcast.net Tel: 904-2 85-6605	SingleJect AutoDisable	3ml	US FDA 510(k): K980078, ISO 7886-4, CE mark	South Korea, China	http://monomedi.en.ec21.com/Single_Ject_Auto_Disable_Syringe--2013825_2013903.html
			5ml	US FDA 510(k): K980078, ISO 7886-4, CE mark		
Neomedic Limited	112-114 Hallowell Road Northwood, Middlesex, HA6 1DU, United Kingdom Contact: Husein M S Gulamhusein hms@neomedic.co.uk Tel:+44 1923 836379 Fax:+44 1923 840160	Neoject	2ml	WHO PQS E13/31, ISO 7886-4, CE Mark	China	http://www.neomedic.co.uk/
			5ml	WHO PQS E13/32, ISO 7886-4, CE Mark		
			10ml	WHO PQS E13/33, ISO 7886-4, CE Mark		
PT Indo Leon	Kompleks Ruko Mega Grosir Cempaka Mas Blok N No. 36 Jalan LetJan Suprapto Jakarta, Indonesia 10640 sales@indoleon.com Tel: 62 (21) 70171967-68 Fax: 62 (21) 4206401	DOSF	3ml	US FDA 510(k): K042102	Indonesia	http://www.indoleon.com/prod_md.htm
PT Oneject Indonesia	Jl. Olympic Raya Rav. B9 Kawasan Industri Sentul Bogor 16810, Indonesia Tel: (62-21) 8791 7422 Fax: (62-21) 8790 2761	K1 Oneject	3ml	WHO PQS E13/19, ISO 7886-4	Indonesia	http://www.alibaba.com/product/id101126094-100761627-0/Auto_Disable_Syringe.html
			5ml	WHO PQS E13/24 ISO 7886-4		

ATTACHMENT A
Safe Injection Supplies
Syringes with Reuse-Prevention Features

Manufacturer	Contact Information	Brand Name	Curative Syringe Size	Certifications (WHO PQS, ISO, GHTF)	Country of Origin	Product Information
Puning Haiou Medical Appliance Co.	Mazha Industrial Area Liusha town, Puning City, Guangdong Province, China Contact: Jacky Lou sales@haiou.net.cn Tel: 0086-663-3883960 Fax: 0086-663-3883968	Tie Shan Lan	2ml	WHO PQS E13/34, ISO 7886-4, CE mark	China	http://www.haiou.net.cn/en/pro.asp
			5ml	WHO PQS E13/35, ISO 7886-4, CE mark		
			10ml	WHO PQS E13/36, ISO 7886-4, CE mark		
Wuxi Yushou Medical Appliances Co. Ltd.	No.215 Xigang Rd, Dongbeitang Town, Wuxi City, Jiangsu Province, China Contact: Fiona Dai dcx@chinasyringe.com	Yushou	3ml	WHO PQS E13/29, ISO 7886-4, CE Mark	China	http://www.chinasyringe.com/en/pro.asp?ClassID=1
Y.P. Precision (M) Sdn. Bhd	Lot 1998-E, Jalan Perusahaan 3, Taman Industri Selesa Jaya, 43300 Balakong, Selangor Darul Ehsan, Malaysia. info@ypprecision.com	SAFEJECT	2ml & 5ml	ISO 13485, ISO 7886-4, CE Mark	Malaysia	http://www.ypprecision.com/05_contact/05_contact.html

NOTES:

- All syringes are 3-piece unless otherwise noted. Prices for RUP syringes are approximately: 2ml = $0.030 to $0.045, 5ml $0.037 to $0.075, and 10ml $0.047 to $0.067.
-This pricing is often dependent upon the volume purchased and may be subject to an order minimum. Additionally this price range does not take into account the costs associated with freight, duty, or clearance.
-When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer. A request for quote should include the syringe size and needle size as part of the specification.

WHO PQS = World Health Organization Performance Quality System
ISO = International Organization for Standardization
GHTF = Global Harmonization Task Force

ATTACHMENT B
Safe Injection Supplies
Syringes with Needlestick-Prevention Features

Manufacturer	Contact Information	Brand Name	NSP Syringe Type	Curative Syringe Size	Certifications (WHO PQS, ISO, GHTF)	Country of Origin	Product Information
Becton Dickinson	1 Becton Drive Franklin Lakes, NJ 07417, USA Contact: Renuka Gadde Renuka_Gadde@bd.com Tel: 201-847-6480 Fax: 201-847-4845	BD SoloMed™	Safety Shield	3ml	WHO PQS E13/21; ISO 7886-4, CE mark	Brazil	http://www.bd.com/products/
				5ml	WHO PQS E13/22; ISO 7886-4, CE mark	Brazil	
		BD Safety-Lok™	Safety Shield	3ml	US FDA 510(k)	USA	http://www.bd.com/hypodermic/pdf/BD_SafetyLok_Brochure.pdf
				5ml	US FDA 510(k)	USA	
				10ml	US FDA 510(k)	USA	
		BD Eclipse™	Safety Shield	3ml	US FDA 510(k) CE Mark	USA	http://catalog.bd.com/bdCat/viewProduct.doCustomer?productNumber=305780
				5ml	US FDA 510(k) CE Mark	USA	
				10ml	US FDA 510(k) CE Mark	USA	
		BD Integra™	Automatic Retractable	3ml	US FDA 510(k) CE Mark	USA	http://www.bd.com/hypodermic/products/integra/index.asp
Inviro Medical	1755 N. Brown Rd Suite 150 Lawrenceville, GA 30044, USA Contact: Karen Dunlap KDunlap@inviromedical.com Tel: 678 405 4030 Fax: 678 405 4044	InviroSNAP!	Manual Retractable	3ml	ISO 7886-4, US FDA 510(k): K092430 CE Mark	Hungary	http://www.inviromedical.com/PRODUCTS/ProductsOverview/tabid/139/Default.aspx
				5ml	ISO 7886-4, US FDA 510(k): K092430 CE Mark	Hungary	
				10ml	ISO 7886-4, US FDA 510(k): K092430 CE Mark	Hungary	
Life-Shield Products, Inc.	3F, No 82-3, Dung Shuen St. Shulin City, Taipei County 238 Taiwan (R.O.C.) Contact: Paul Lin sales@lifeshield-careo.com Tel: 886-2-86848000 Fax: 886-2-86844000 www.lifeshield-careo.com	Careo Safety Syringe	Manual Retractable	3ml	ISO 7886-4, CE mark, US FDA 510(k): K052397	Taiwan	http://www.lifeshield-careo.com/EN/products.htm
				5ml	ISO 7886-4, CE mark, US FDA 510(k): K052397	Taiwan	
				10ml	ISO 7886-4, CE mark, US FDA 510(k): K052397	Taiwan	

ATTACHMENT B
Safe Injection Supplies
Syringes with Needlestick-Prevention Features

Manufacturer	Contact Information	Brand Name	NSP Syringe Type	Curative Syringe Size	Certifications (WHO PQS, ISO, GHTF)	Country of Origin	Product Information
Medical Device Manufacturer Ltd.	10th Floor, President Tower 973 Ploenchit Road Lumpini, Pathumwan Bangkok 10330 Contact: Ms. Wirawan Suttaharutai wirawan@mdmthailand.com Tel: 66 2 939 2713 Fax: 66 2 939 2713	ClickZip™ Needle Retractable Safety Syringe	Manual Retractable	3ml	CE Mark, US FDA 510(k): K051694	China	http://clickzipsafetysyringe.com/Home_Page.html
				5ml	CE Mark, US FDA 510(k): K051695	China	
Puning Haiou Medical Appliance Co.	Mazha Industrial Area Liusha town, Puning City, Guangdong Province, China Contact: Jacky Lou	Needle Retractable Safety Syringe	Manual Retractable	3ml	CE Mark	China	http://www.haiou.net.cn/en/pro.asp
				5ml	CE Mark	China	
				10ml	CE Mark	China	
Retractable Technologies, Inc.	511 Lobo Lane Little Elm, Texas 75068, USA Contact: Kathryn Duesman rticlinical@vanishpoint.com Tel: 888-703-1010 Fax: 972-221-9786	VanishPoint	Automatic Retractable	3ml	WHO PQS E13/09, ISO 7886-4, CE mark	China and USA	http://www.vanishpoint.com/Simple4.aspx?PageId=182
				5ml	WHO PQS E13/08, ISO 7886-4, CE mark	China and USA	
				10ml	WHO PQS E13/07, ISO 7886-4, CE mark	China and USA	
Uniqsafe Biomeditech Co. (Supplier: Axel Bio Corp.)	P.O. Box 910640 San Diego, CA 92191, USA Contact: Michael Wu, PhD mwu@axelbio.com Tel: 858-653-0084 Fax: 619-768-2458	UniqSafe® Retractable Safety Syringe	Manual Retractable	3ml	CE mark, US FDA 501(k)	China & Taiwan	http://www.axelbio.com/uniqsafe-syringe.htm
				5ml	CE mark, US FDA 501(k)	China & Taiwan	
				10ml	CE mark, US FDA 501(k)	China & Taiwan	
Safety 1st Medical	1740 E. Garry Ave, Ste. 109, Santa Ana, CA 92705, USA Contact:Dan Daley ddaley@safety1stmedical.com Tel: 949-476-5555, ext 202 Fax: 949-476-5559	Safe-1 Safety Syringe	Automatic Retractable	3ml	US FDA 510(k): K940635 ISO 7886-4	USA	http://www.safety1stmedical.com/safety.html
				10ml	US FDA 510(k): K940635 ISO 7886-5	USA	

ATTACHMENT B
Safe Injection Supplies
Syringes with Needlestick-Prevention Features

Manufacturer	Contact Information	Brand Name	NSP Syringe Type	Curative Syringe Size	Certifications (WHO PQS, ISO, GHTF)	Country of Origin	Product Information
Terumo	Researchpark Haasrode 1520 Interleuvenlaan 40 - 3001 Leuven, Belgium Contact: Connie Huygens Connie.Huygens@terumo-europe.com	SurGuard2	Safety Shield	3ml	contact manufacturer	Belgium	http://www.terumotmp.com/ProductDetails.aspx?ApplicationId=1&productId=156
				5ml	contact manufacturer	Belgium	
				10ml	contact manufacturer	Belgium	

NOTES:

- Prices for RUP with NSP syringes are approximately: 2ml = $0.058 to $0.379, 5ml $0.058 to $0.17, and 10ml $0.062 to $0.028.
- This pricing is often dependent upon the volume purchased and may be subject to an order minimum. Additionally this price range does not take into account the costs associated with freight, duty, or clearance.
- When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer. A request for quote should include the syringe size and needle size as part of the specification.

WHO PQS = World Health Organization Performance Quality System;
ISO = International Organization for Standardization;
GHTF = Global Harmonization Task Force

Attachment C
Safe Injection Supplies
Insulin Syringes

Manufacturer	Contact Information	Brand Name	Syringe Type	Insulin Syringe Size	Certifications (ISO, GHTF)	Country of Origin	Product Information
Becton Dickinson	1 Becton Drive Franklin Lakes, NJ 07417 Contact: Renuka Gadde Renuka_Gadde@bd.com Tel: 201-847-6480 Fax: 201-847-4845	BD Insulin Syringe	Standard Disposable	1 ml (29G x 1/2")	US FDA 510(k)	contact manufacturer	http://www.bd.com/hypodermic/products/BDInsulinSyringewithPermanentNeedle.asp
		BD Integra	RUP with NSP Automatic Retractable	1ml (29G x 1/2")	contact manufacturer	contact manufacturer	http://catalog.bd.com/bdCat/search.doCustomer?searchText=305282&typeOfSearch=0&viewPageNum=0&sortByField=Category
		BD Safety-Lok	RUP with NSP Safety Shield	1ml (29G x 1/2")	contact manufacturer	contact manufacturer	http://catalog.bd.com/bdCat/search.doCustomer?searchText=329464+&typeOfSearch=0&viewPageNum=0&sortByField=Category
		BD SafetyGlide	RUP with NSP Safety Shield	1ml (29G x 1/2")	contact manufacturer	contact manufacturer	http://catalog.bd.com/bdCat/search.doCustomer?searchText=305930&typeOfSearch=0&viewPageNum=0&sortByField=Category
Hindustan Syringes & Medical Devices, Ltd.	174, Sector 25 Ballabgarh, India 121004 Contact: Rajiv Nath hmdhealthcare@vsnl.com Tel: 91-11-23314758 Fax: 91-11-23313569	Dispo Van	Standard Disposable	1ml (29G x 1/2")	ISO 8537	India	http://www.hmdhealthcare.com/asian/is.htm?referringurl=http%3A//www.hmdhealthcare.com/asian/home1.htm
Inviro Medical	1755 N. Brown Rd Suite 150 Lawrenceville, GA 30044, USA Contact: Karen Dunlap KDunlap@inviromedical.com Tel: 678 405 4030 Fax: 678 405 4044	InviroSNAP!	RUP with NSP Manual Retractable	1ml (29G x 1/2" and 28G x 1/2")	ISO 8537, US FDA 510(k): K092413	China	http://www.inviromedical.com/PRODUCTS/SNAPSafetySyringe/InsulinSyringes/tabid/327/Default.aspx
Medical Device Manufacturer Ltd.	10th Floor, President Tower 973 Ploenchit Road Lumpini, Pathumwan Bangkok 10330, Thailand Contact: Ms. Wirawan Suttaharutai wirawan@mdmthailand.com Tel: 66 2 939 2713 Fax: 66 2 939 2713	ClickZip™ Needle Retractable Safety Syringe	RUP with NSP Manual Retractable	1ml (27G x 1/2", 29G x 1/2", 27G x 5/16", 29G x 5/16")	ISO 8537, CE mark, US FDA 510(k): K050134	China	http://clickzipsafetysyringe.com/Home_Page.html
MoniMedi Korea Co., Ltd	#439 -14, Gakyo-ri Songak-myun Dangjin-gun Chungcheongnam-do Korea Contact: Rudy Mah e-mail: marketing@monomedikorea.com Tel: 82 - 41 - 3567460 Fax: 82 - 41 - 3567463 US contact: Ken Ulerick e-mail: nanken@comcast.net Tel: 904-2 85-660	Monoject	RUP	1 ml; (29G x 1/2", 30G x 1/2")	ISO 8537, US FDA 510(k): K980078	South Korea, China	http://monomedi.en.ec21.com/Monoinject_U100_Insulin_Syringe--2013825_2013872.html

Attachment C
Safe Injection Supplies
Insulin Syringes

Manufacturer	Contact Information	Brand Name	Syringe Type	Insulin Syringe Size	Certifications (ISO, GHTF)	Country of Origin	Product Information
Retractable Technologies, Inc.	511 Lobo Lane Little Elm, Texas 75068, USA Contact: Kathryn Duesman rticlinical@vanishpoint.com Tel: 888-703-1010 Fax: 972-221-9786	VanishPoint	RUP with NSP Automatic Retractable	1 ml (29G x 1/2")	ISO 8537, US FDA 510(k): K97330, 1CE mark	US and China	http://www.vanishpoint.com/files/Syringe_Brochure.pdf
Smiths Medical	2231 Rutherford Rd Carlsbad, CA 92008 Phone: 800-426-2448 Phone: 760-602-4400 Email: info.cc@smiths-medical.com	Needle-Pro	RUP with NSP Safety Shield	1ml (26G x 1/2"; 27G x 1/2"; 30g x 1/2")	CE mark	contact manufacturer	http://www.smiths-medical.com/catalog/injections/insulin-allergy/fixed-insulin/hypodermic-needle-pro-device-3.html
Terumo	Researchpark Haasrode 1520 Interleuvenlaan 40 - 3001 Leuven, Belgium Contact: Connie Huygens	Terumo	Standard disposable	1ml (29G x 1/2" and 27G x 1/2")	contact manufacturer	contact manufacturer	http://www.terumotmp.com/ProductDetails.aspx?categoryId=5&productId=404
		SurGuard	RUP with NSP Safety Shield	1ml (29G x 1/2" and 28G x 1/2")	contact manufacturer	contact manufacturer	http://www.terumotmp.com/ProductDetails.aspx?categoryId=5&productId=239

NOTES:

- There are many high-quality single-use insulin syringes that meet ISO standards available on the current market. The above syringes and manufacturers are provided as an example only.

- Prices for insulin syringes range from approximately: $0.040 to $0.068 (standard) and $0.113 to $.140 (safety). This pricing is often dependent upon the volume purchased and may be subject to an order minimum. Additionally this price range does not take into account the costs associated with freight, duty, or clearance.
- When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer.
- A request for quote should include the syringe size, needle size, and specific U-100 or U-40 as part of the specification.

ISO = International Organization for Standardization;
GHTF = Global Harmonization Task Force

ATTACHMENT D
Safe Injection Supplies
Cardboard Safety Boxes and Sharps Containers

Manufacturer	Contact Information	Brand Name	Specifications	Certifications (WHO PQS)	Country of Origin	Product Information
Hindustan Syringes & Medical Devices, Ltd.	174, Sector 25 Ballabgarh, India 121004 Contact: Rajiv Nath hmdhealthcare@vsnl.com Tel: 91-11-23314785 Fax: 91-11-23313569	KOJAK Safety Box	Volume: 5 litres Capacity: up to 65 5-ml syringes Assembled dimensions: 285 x 160 x 125 mm Directions: Russian, Spanish, English, French & pictorial	Subject to WHO review in 2010: WHO PQS E10/06; WHO–PQS E10/SB01.1 Performance Standard	India	http://www.hmdhealthcare.com/usa/SafetyBox.htm?referringurl=http%3A//www.hmdhealthcare.com/usa/home1.htm
			Volume: 10 litres Capacity: up to 120 5-ml syringes Directions: Russian, Spanish, English, French & pictorial	WHO–PQS E10/SB01.1 Performance Standard	India	
Pa-Hu Oy	Teolisuustie 2 FIN-02880 Veikkola Finland Contact: Ilkka Raikamo ilkka.Raikamo@pa-hu.fi Tel: 358-20 7891000 Fax: 358-20 7891099	Safety Box	Volume: 5 litres Capacity: 150 - .5l syringes Assembled dimensions: 315 x 128 x 145 mm Directions on box: Russian, Spanish, English, French & pictorial, other languages available	Subject to WHO review in 2010: WHO PQS E10/04; WHO–PQS E10/SB01.1 Performance Standard	Finland	http://www.who.int/immunization_standards/vaccine_quality/PQS_E10_07_5L_safetybox_pahuoy.pdf

ATTACHMENT D
Safe Injection Supplies
Cardboard Safety Boxes and Sharps Containers

Manufacturer	Contact Information	Brand Name	Specifications	Certifications (WHO PQS)	Country of Origin	Product Information
Polynor AS	Brennerigt. 3, P.O. Box 1273 N-2806 Gjovik, Norway Contact: Ester Smedhaugen ester@polynor.no Tel: (47) 61 13 89 30 Fax: (47) 61 13 89 40	PolySafe Safety Box	Volume: 5 litres Capacity: 155 0.5-ml AD syringes Assembled dimensions: 285 x 160 x 130 mm Directions on box: Russian, Spanish, English, French & pictorial	WHO PQS E10/01; WHO–PQS E10/SB01.1 Performance Standard	Norway	http://www.who.int/immunization_standards/vaccine_quality/PQS_E10_01_5L_safetybox.pdf
			Volume: 10 litres Capacity: 326 0.5-ml AD syringes Assembled dimensions: 305 x 245 x 150 mm Directions on box: Russian, Spanish, English, French & pictorial	WHO PQS E10/02; WHO–PQS E10/SB01.1 Performance Standard	Norway	http://www.who.int/immunization_standards/vaccine_quality/PQS_E10_02_10L_safetybox.pdf
			Volume: 15 litres Capacity: 450 0.5-ml AD syringes Assembled dimensions: 310 x 240 x 210 mm Directions on box: Russian, Spanish, English, French & pictorial	WHO PQS E10/03; WHO–PQS E10/SB01.1 Performance Standard	Norway	http://www.who.int/immunization_standards/vaccine_quality/PQS_E10_03_15L_safetybox.pdf
Smurfit Kappa Lagamill AB	P.O Box 43 SE-285 21 Markaryd Sweden Contact: Boo Sjolin Boo.Sjolin@smurfitkappa.se Telephone: +46 433 181 00 Fax: +46 433 125 45	timSafe Safety Box	Volume: 5 litres Capacity: 130 .5-ml syringes Assembled dimensions: 311 x 154 x 112 mm Directions: Russian, Spanish, English, French, and pictorial directions.	Subject to WHO review in 2010: WHO PQS E10/05; WHO–PQS E10/SB01.1 Performance Standard	Sweden	http://www.who.int/immunization_standards/vaccine_quality/PQS_E10_05_5L_safetybox_smurfitkappa0409.pdf

NOTES:

- Prices for safety boxes range from approximately: 2.5L = $1.40, 5L = $0.72 to $2.50, and 10L = $2.92. This pricing is often dependent upon the volume purchased and may be subject to an order minimum. Additionally this price range does not take into account the costs associated with freight, duty, or clearance.
- When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer.

WHO PQS = World Health Organization Performance Quality System

ATTACHMENT E
Safe Injection Supplies
Blood Collection Needles, Tube Holders, Winged Blood Collection Sets

Manufacturer	Contact Information	Brand Name	Description	Part Number(s) and Needle Gauge / Length	Certifications (ISO, GHTF)	Country of Origin	Product Information
Blood Collection Needles and Tube Holders							
Becton Dickinson	One Becton Dr. Franklin Lakes, NJ 07417 Phone: 888/237-2762 Phone: 201/847-6800 Fax: 201/847-6475	BD Vacutainer Eclipse Blood Collection Needle	Blood collection needle with Luer adapter	368607 - 21 G x 1.25" 368608 - 22 G x 1.25"	US FDA 510(k) CE Mark	USA	http://www.bd.com/vacutainer/products/venous/eclipse_bcn_docs.asp
			As above with pre-attached BD Vacutainer® One-Use Holder	368650 - 21 G x 1.25" 368651 - 22 G x 1.25"	US FDA 510(k) CE Mark	USA	
		BD Vacutainer® One-Use Holder	Single-use, shielded blood collection tube holder compatible with BD Vacutainer® Eclipse™ Blood Collection Needles, BD Vacutainer® Safety-Lok™ Blood Collection Sets, BD Vacutainer® Push Button Blood Collection Sets, and the BD Vacutainer® Multiple Sample Luer Adapters.	364815 - see size compatibility under 'Description'	US FDA 510(k) CE Mark	USA	http://www.bd.com/vacutainer/pdfs/VS7189_BD_Vacutainer_One_Use_Holder.pdf
		BD Vacutainer Passive Shielding Blood Collection Needle with Integrated Blood Tube Holder	Blood collection needle and tube holder with an integrated safety shield that fully covers needle after use.	368636 - 21 G x 1" 368637 - 22 G x 1"	US FDA 510(k) CE Mark	USA	http://www.bd.com/vacutainer/pdfs/VS7074_Passive_Shielding_BCN_brochure.pdf

ATTACHMENT E
Safe Injection Supplies
Blood Collection Needles, Tube Holders, Winged Blood Collection Sets

Manufacturer	Contact Information	Brand Name	Description	Part Number(s) and Needle Gauge / Length	Certifications (ISO, GHTF)	Country of Origin	Product Information
Covidien	15 Hampshire Street Mansfield, MA 02048 Phone: 800/962-9888	Defender Safety Needle Holder	Single-use, retractable blood collection tube holder.	8881225110 - 1" 8881225115 - 1.5"	US FDA 510(k)	USA	http://www.kendallhealthcare.com/kendallhealthcare/pageBuilder.aspx?contentID=68682&webPageID=0&topicID=68675&breadcrumbs=0:121623,81034:0,68674:0#Features%20and%20Benefits
		Magellan™ Safety Blood Collection Device	Single-use blood tube holder, collection needle, and safety device.	8881225121 - 21G x 1" 8881225122 - 22G x 1" 8881226121 - 21G x 1.25" 8881226122 - 22G x 1.25"	US FDA 510(k)	USA	http://www.kendallhealthcare.com/kendallhealthcare/pageBuilder.aspx?contentID=70235&webPageID=0&topicID=70229&breadcrumbs=0:121623,81034:0,68674:0#Features%20and%20Benefits
		PROGUARD™ II Safety Needle Holder	Single-use, shielded blood collection tube holder.	8881225100 - 1" 8881225150 - 1"	US FDA 510(k)	USA	http://www.kendallhealthcare.com/kendallhealthcare/pageBuilder.aspx?contentID=76733&webPageID=0&topicID=76727&breadcrumbs=0:121623,81034:0,68674:0#Features%20and%20Benefits
Gaven Medical	129 Reservoir Rd Vernon, CT 06066 Fax: 860-870-6118 Phone: 860-870-6112	Punctur-Guard Blood Collection Needle	Blood collection needle. Hollow, blunt cannula within an otherwise standard needle. The blunt cannula is advanced and locked into place beyond the sharp tip of the outer needle before removal from patient.	4212 - 21 G x 1" 4214 - 21 G x 1.5" 4222 - 22 G x 1"	US FDA 510(K): K895024, CE mark	USA	http://www.gavenmedical.com/HumanBioMedicalProducts.html
Greiner Bio-One	Bad Haller Straße 32 A-4550 Kremsmünster Austria Phone: +43 7583 6791-0 Fax: +43 7583 6318 E-Mail: office@at.gbo.com	VACUETTE® QuickShield Tube Holder	Single-use, disposable blood collection tube holder with safety cap activated using one hand immediately after blood collection .	450230	ISO 6710 EN 14820:2004 FDA Clearance CE Mark	Austria	http://www.gbo.com/en/index_2048.php
		VACUETTE® QuickShield Complete	VACUETTE® QuickShield Tue Holder and Multiple Use Drawing Needle	450237 - 21 G x 1.5" 450238 - 21 G x 1"	ISO 6710 EN 14820:2004 FDA Clearance CE Mark	Austria	http://www.gbo.com/documents/IFU_QuickShield_Complete_GB_rev00.pdf
ITL	ITL Australia (Head Office) 1/63 Wells Road, Chelsea Heights, 3196 Victoria AUSTRALIA Email: sales@itl-limited.com	Samplok® Tube Holders	Single-use, blood collection tube holder , with pre-attached multisample luer adapter available with or without hinged lid.	multiple products available, compatible for use with blood collection sets from all major manufacturers	contact manufacturer	Malaysia	http://www.itl-limited.com/pr_samplok.php

ATTACHMENT E
Safe Injection Supplies
Blood Collection Needles, Tube Holders, Winged Blood Collection Sets

Manufacturer	Contact Information	Brand Name	Description	Part Number(s) and Needle Gauge / Length	Certifications (ISO, GHTF)	Country of Origin	Product Information
Retractable Technologies, Inc.	P O Box 9 511 Lobo Lane Little Elm, Tx 75068-0009 Phone: 888/703-1010 Phone: 888/806-2626 Fax: 972/294-4400	VanishPoint Blood Collection Tube Holder	Single-use automatic retractable blood collection tube	tube holder is compatible with conventional blood collection needles	US FDA 510(K): K971763, CE mark	USA	http://www.vanishpoint.com/files/BCTH_Brochure.pdf
Sarstedt, Inc.	SARSTEDT AG & Co. Rommelsdorfer Straße Postfach 1220 51582 Nümbrecht Germany Tel.: +49 2293 305 0 Fax: +49 2293 305 282 E-mail: info@sarstedt.com	S-Monovette needle	Single-use shielded blood collection needle, for use with S-Monovette® closed blood collection system	85.1160 - 0.9mm /38mm; 20 G x 1.5” 85.1162 - 0.8mm /38mm; 21 G x 1.5” 85.1440 - 0.7mm /38mm; 22 G x 1.5” 85.1162.400 - 0.8mm /38mm; 21 G x 1.5”	US FDA 510(K): K051019, CE Mark	Germany	http://www.sarstedt.com/pdf/katalog/en/PF-117.pdf
Smiths Medical	2231 Rutherford Rd Carlsbad, CA 92008 Phone: 800-426-2448 Phone: 760-602-4400 Email: info.cc@smiths-medical.com	Saf-T Holder® Devices	Single-use retractable blood collection tube, available separately or with Saf-T Wing® Blood Collection Sets	96000 - w/ male Luer adapter 96002 - w/ female Luer adapter 96007 - Pediatric tube insert	US FDA 510(k) CE Mark	USA UK Mexico or Italy	Saf-T Holder® Devices
		Venipuncture Needle-Pro® Device	Single-use shielded blood tube holder.	4140 - Individual Bags of 25 4141 - Bulk Pack	US FDA 510(k) CE Mark	USA UK Mexico or Italy	Venipuncture Needle-Pro® Device
		Blood Draw Hypodermic Needle-Pro® Device	Blood collection needle compatible with Luer slip and Luer lock syringes.	4270 - 20 G x 1.5" 4271 - 20 G x 1" 4272 - 21 G x 1.5" 4273 - 21 G x 1" 4274 - 22 G x 1.5" 4275 - 22 G x 1" 4276 - 23 G x 1" 4277 - 25 G x 5/8" 4278 - 25 G x 1"	US FDA 510(k) CE Mark	USA UK Mexico or Italy	Blood Draw Hypodermic Needle-Pro® Device

ATTACHMENT E
Safe Injection Supplies
Blood Collection Needles, Tube Holders, Winged Blood Collection Sets

Manufacturer	Contact Information	Brand Name	Description	Part Number(s) and Needle Gauge / Length	Certifications (ISO, GHTF)	Country of Origin	Product Information
Winged (Butterfly) Blood Collection Sets							
Becton Dickinson	One Becton Dr. Franklin Lakes, NJ 07417 Phone: 888/237-2762 Phone: 201/847-6800 Fax: 201/847-6475	BD Vacutainer® Push Button Blood Collection Set	Winged safety push button blood collection set; available with or without pre-attached holder	367344 With Luer, 21g 3/4" - 12" Tubing 367342 With Luer, 23g 3/4" - 12" Tubing 367341 With Luer, 25g 3/4" - 12" Tubing 367338 With Luer, 21g 3/4" - 7 " Tubing 367336 With Luer, 23g 3/4" - 7 " Tubing 367335 With Luer, 25g 3/4" - 7 " Tubing 367326 Without Luer, 21g 3/4" - 12" Tubing 367324 Without Luer, 23g 3/4" - 12" Tubing	US FDA 510(k)	USA	http://www.bd.com/vacutainer/pdfs/VS7024_BD_vacutainer_Push_Button_bc.pdf
		BD Vacutainer® Safety-Lok™ Blood Collection Set	Winged safety shielded blood collection set, can be used for infusion	367281 With Luer, 21g 3/4" - 12" Tubing 367283 With Luer, 23g 3/4" - 12" Tubing 367285 With Luer, 25g 3/4" - 12" Tubing 367287 With Luer, 21g 3/4" - 7 " Tubing 367292 With Luer, 23g 3/4" - 7 " Tubing 367294 With Luer, 25g 3/4" - 7 " Tubing 367296 Without Luer, 21g 3/4" - 12" Tubing 367297 Without Luer, 23g 3/4" - 12" Tubing	US FDA 510(k)	USA	http://www.bd.com/vacutainer/pdfs/safety-lok_bcs_VS5116.pdf
Covidien	15 Hampshire Street Mansfield, MA 02048 Phone: 800/962-9888	MONOJECT™ ANGEL WING™ Blood Collection Sets with Needle Holder	Winged safety shielded blood collection set	8881225265 - w/ Needle Holder 23 X 3/4" 8881225221 - w/ Needle Holder 21 X 3/4" 8881225273 - w/ Needle Holder 25 X 3/4"	US FDA 510(k)	USA	MONOJECT™ ANGEL WING™ Blood Collection Sets with Needle Holder Features and Benefits
Gaven Medical	129 Reservoir Rd Vernon, CT 06066 Fax: 860-870-6118 Phone: 860-870-6112	Punctur-Guard Winged Set for Blood Collection	Winged blood collection set with hollow, blunt cannula within an otherwise standard needle. The blunt cannula is advanced and locked into place beyond the sharp tip of the outer needle before removal from patient. MSLA or End Cap configurations	Multiple part numbers: 25g, 23g, 21g, 19g Tubing Lengths - 6", 12"	US FDA 510(K): K003827, CE mark	USA	http://www.gavenmedical.com/HumanBioMedicalProducts.html
Greiner Bio-One	Bad Haller Straße 32 A-4550 Kremsmünster Austria Phone: +43 7583 6791-0 Fax: +43 7583 6318 E-Mail: office@at.gbo.com	VACUETTE® Safety Blood Collection Sets	Winged manual retractable blood collection set; with or without Luer Adapter, or with Luer Adapter and Holder or with Blood Culture Holder.	450091- 19cm tube, 21G x 3/4" 450092- 19cm tube 23G x 3/4"	ISO 6710, US FDA 510(k), CE Mark	Austria	http://www.gbo.com/documents/980204_SBCS_GB_rev03.pdf

ATTACHMENT E
Safe Injection Supplies
Blood Collection Needles, Tube Holders, Winged Blood Collection Sets

Manufacturer	Contact Information	Brand Name	Description	Part Number(s) and Needle Gauge / Length	Certifications (ISO, GHTF)	Country of Origin	Product Information
Hindustan Syringes & Medical Devices, Ltd.	174/25, Ballabgarh, Faridabad (Haryana) - 121 004 India Ph: +91-129-2232378, Fax:+91-129-2233242, hmdhealthcare@vsnl.com www.hmdhealthcare.com	VAKU-8 Plus Safety Blood Collection Set	Winged safety shielded blood collection set	SVMSP-21 -12in tube, 21G x 3/4" SVMSP-23 12in tube, 23G x 3/4" SVMSP-25 12in tube, 25G x 3/4"	US FDA 510(K): K000592 CE Mark	India	Vaku-8
Kawasumi Laboratories America, Inc.	P O Box 24355 Tampa, FL 33623-4355 Phone: 813/630-5554 Fax 813/630-5033	K-Shield Winged Needle Blood Collection Set	Winged safety shielded blood collection set	with Multi-Sample Luer Adapter DBMS-21G 12in tube, 21G x 3/4" DBMS-23G 12in tube, 23G x 3/4" DBMS-25G 12in tube, 25G x 3/4"	US FDA 510(k)	Thailand	Winged Blood Collection Sets
Sarstedt, Inc.	SARSTEDT AG & Co. Rommelsdorfer Straße Postfach 1220 51582 Nümbrecht Germany Tel.: +49 2293 305 0 Fax: +49 2293 305 282 E-mail: info@sarstedt.com	Multifly® needle	Winged safety shielded needle for use with S-Monovette® closed blood collection system	85.1637.035 - 0.9mm /19mm; 20Gx 3/4" 85.1638.035 - 0.8mm /19mm; 21Gx 3/4" 85.1637.005 - 0.9mm /19mm; 20Gx 3/4" 85.1638.005 - 0.8mm /19mm; 21Gx 3/4" 85.1640.005 - 0.6mm /19mm; 23Gx 3/4" 85.1642.005 - 0.5mm /19mm; 25Gx 3/4" 85.1638* - 0.8mm /19mm; 21Gx 3/4"	US FDA 510(K): K032150, CE Mark	Germany	http://www.sarstedt.com/pdf/katalog/en/PF-117.pdf
Terumo Medical Corp.	2101 Cottontail Lane Somerset, NJ 08873 Phone: 800/326-6457 Fax: 732/302-3093 E-mail: safety.sharps@medical.com	Surshield™ Safety Winged Blood Collection Set	Winged safety shielded blood collection set	MN*SVS21B30 - 21G x 3/4" w/12" tubing MN*SVS23B30 - 23G x 3/4" w/12" tubing MN*SVS25B30 - 25G x 3/4" w/12" tubing MN*SVS21B18 - 21G x 3/4" w/7" tubing MN*SVS23B18 - 23G x 3/4" w/7" tubing	US FDA 510(k) CE Mark	China USA	http://www.terumotmp.com/pdf/SurshieldSafety.pdf
NOTES:							

- Prices for blood collection needles range from approximately $0.28 to $0.59, blood collection tubes range from approximately $0.05 to $1.81, blood collection systems (needle and tubes) range from approximately $0.60 to $1.85, and winged blood collection systems (needle and tubes) range from approximately $0.90 to $2.20. This pricing is often dependent upon the volume purchased and may be subject to an order minimum. Additionally this price range does not take into account the costs associated with freight, duty, or clearance.
-When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer.
- A request for quote should include the needle size as part of the specification.

ISO = International Organization for Standardization
GHTF = Global Harmonization Task Force

ATTACHMENT F
Safe Injection Supplies
IV Insertion and Infusion

Manufacturer	Contact Information	Brand Name	Description	Part Number(s) and Needle Gauge / Length	Certifications (ISO, GHTF)	Country of Origin	Product Information
Peripheral Intravenous (IV) Catheters							
B. Braun Medical Inc.	824 12th Ave. Bethlehem, PA 18018 Tel: 800/227-2862 Tel: 610/691-5400 Fax: 610/691-6249	Introcan® Safety™ IV Catheter	Shielded catheter with self-activating protection, safety clip covers needle tip immediately after use; available with and without wings, polyurethane or FEP	4251687-02 - 18x1-1/4" I4251644-022 - 20x1-1/4" 4251601-02 - 24gX3/4"	US FDA 510(k) CE Mark	Germany	http://www.bbraun.com/service-layer-core/res/document/BPR0000000000000001000000073702000/47E8AFBF96FA024DE1008000D400106F47E8AFC196FA024DE1008000D400106F?vc=CORPORATE_WEBSITE
Becton Dickinson	One Becton Dr. Franklin Lakes, NJ 07417 Tel: 888/237-2762 Tel: 201/847-6800 Fax: 201/847-6475	BD Insyte™ Autoguard™ Shielded IV Catheters	Push-button shielding mechanism releases the spring and allows the needle and flash chamber to retract into the safety barrel; also available BD Insyte-N™ Autoguard™ Shielded IV Catheter for neonates	Multiple gauges, needle sizes and flow rates. Available winged or non-winged	US FDA 510(k) CE Mark	USA	http://www.bd.com/infusion/pdfs/D16128.pdf
		BD Saf-T-Intima™ Closed IV Catheter System	Closed IV catheter with a telescoping needle shield that passively covers the stylet as it is withdrawn from the catheter,	383312 - 24 g x 0.75" 383313 - 24 g. x 0.75". w/ Y adapter 383322 - 22 g x 0.75" 383323 - 22 g x 0.75" w/ Y adapter 383335 - 20 g x 1.00". 383336 - 20 g x 1.00" w/ Y adapter 383346 - 18 g x 1.00" w/ Y adapter	US FDA 510(k) CE Mark	Mexico	http://www.bd.com/infusion/pdfs/D14441.pdf
Retractable Technologies, Inc.	P O Box 9 511 Lobo Lane Little Elm, Tax 75068-0009 Tel: 888/703-1010 Tel: 888/806-2626 Fax: 972/294-4400	VanishPoint® IV Catheter	Automatic retractable	31221 - 24G x 3/4" 31331 - 22G x 1" 31441 - 20G x 1 1/4" 31541 - 18G x 1 1/4"	ISO 10555-1, ISO 10555-5, US FDA 510(K): K081420, CE mark	USA	http://www.vanishpoint.com/files/IV_Cath_Brochure_2006.pdf
Smiths Medical	2231 Rutherford Rd Carlsbad, CA 92008 Tel: 800/426-2448 Tel: 760/602-4400	ADVANTIV® Safety I.V. Catheters	Fully encased needle tip with a passive design	3123 - 24G x 5/8" 3152 - 16G x 2" 3154 - 18G x 1 3/4" 3158 - 14G x 2" 3159 - 20G x 1 3/4" 3160 - 22G x 1" 3162 - 16G x 1 1/4" 3165 - 18G x 1 1/4" 3166 - 20G x 1 1/4" 3167 - 20G x 1" 3168 - 14G x 1/4"	US FDA 510(k) CE Mark	USA UK Mexico or Italy	http://www.smiths-medical.com/upload/products/PDF/VA7001.pdf

ATTACHMENT F
Safe Injection Supplies
IV Insertion and Infusion

Manufacturer	Contact Information	Brand Name	Description	Part Number(s) and Needle Gauge / Length	Certifications (ISO, GHTF)	Country of Origin	Product Information
		PROTECTIV® Safety I.V. Catheters	Manual retractable IV catheter	Multiple gauges, needle sizes and flow rates. Available winged or non-winged	US FDA 510(k) CE Mark	USA UK Mexico or Italy	http://www.smiths-medical.com/upload/products/PDF/ProtectIVBrochure.pdf
Terumo Medical Corp.	2101 Cottontail Lane Somerset, NJ 08873 Tel: 800/326-6457 Fax: 732/302-3093 E-mail: safety.sharps@medical.com	Surshield® Safety I.V. Catheter	Fully encased needle tip with a passive design	SR*SFA1832A - 18G x 1 1/4" SR*SFA2032A - 20G x 1 1/4" SR*SFA2225A - 22G x 1" SR*SFA2419A - 24G x 3/4"	US FDA 510(k) CE Mark	China USA	http://www.terumotmp.com/pdf/Surshield%20Catheter%20Brochure_latestrev.pdf

ATTACHMENT F
Safe Injection Supplies
IV Insertion and Infusion

Manufacturer	Contact Information	Brand Name	Description	Part Number(s) and Needle Gauge / Length	Certifications (ISO, GHTF)	Country of Origin	Product Information
Winged (Butterfly) Infusion Sets							
Covidien	15 Hampshire Street Mansfield, MA 02048 Tel: 800/962-9888	MONOJECT™ ANGEL WING™ Blood Collection / Infusion Set	Winged safety shielded blood collection / infusion set	8881225174 w/ Female Luer 19 X 3/4" 8881225182 w/ Female Luer 21 X 3/4" 8881225190 w/ Female Luer 23 X 3/4" 8881225208 w/ Female Luer 25 X 3/4" 8881225390 w/ Female Luer 23 X 3/4" 8881225782 w/ Female Luer 21 X 3/4"	US FDA 510(k)	USA	http://www.kendallhealthcare.com/kendallhealthcare/pageBuilder.aspx?contentID=105247&webPageID=0&topicID=74908&breadcrumbs=0:121623,81034:0,68663:0
Gaven Medical	129 Reservoir Rd Vernon, CT 06066 Fax: 860-870-6118 Phone: 860-870-6112	Punctur-Guard Winged Set for Infusion	Winged infusion set with hollow, blunt cannula within an otherwise standard needle. The blunt cannula is advanced and locked into place beyond the sharp tip of the outer needle before removal from patient. MSLA or End Cap configurations	Multiple part numbers: 25g, 23g, 21g, 19g Tubing Lengths - 6", 12"	US FDA 510(K): K961251, CE mark	USA	http://www.gavenmedical.com/HumanBioMedicalProducts.html
MYCO Medical Supplies, Inc.	113 Centre West Court Cary, NC 27513 Phone: 800/454-6926 FAX: 919/677-1445 Email: sales@mycomedical.com	Unolok-Plus Safety Infusion Set	winged with manual shield locks into place	7001P-19 - 19G x ¾"; 12" tubing 7001P-21 - 21G x ¾"; 12" tubing 7001P-23 - 23G x ¾"; 12" tubing 7001P-25 - 25G x ¾"; 12" tubing	contact manufacturer	contact manufacturer	http://www.mycomedical.com/UNOLOKPlusInfusionSets.html
Terumo Medical Corp.	2101 Cottontail Lane Somerset, NJ 08873 800/326-6457 FAX 732/302-3093 E-mail: safety.sharps@medical.com	Surshield™ Safety Winged Infusion Sets	winged with manual shield locks into place	SV*S19BL - 19G x 3/4"; 12" Tubing SV*S21BL - 21G x 3/4"; 12" Tubing SV*S23BL - 23G x 3/4"; 12" Tubing SV*S25BL - 25G x 3/4"; 12" Tubing SV*S19BLS - 19G x 3/4"; 3 1/2" Tubing SV*S21BLS - 21G x 3/4"; 3 1/2" Tubing SV*S23BLS - 23G x 3/4"; 3 1/2"	US FDA CE Mark	China USA	http://www.terumotmp.com/pdf/SurshieldSafety.pdf

NOTES:

-Prices for peripheral IV catheters range from approximately $1.20 to $4.49 and winged infusions sets range from approximately $0.81 to $1.23. This pricing is often dependent upon the volume purchased and may be subject to an order minimum. Additionally this price range does not take into account the costs associated with freight, duty, or clearance.

-When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer.

GHTF = Global Harmonization Task Force

ATTACHMENT G
Safe Injection Supplies
Capillary Blood Collection

Manufacturer	Contact Information	Brand Name	Description	Tube size	Certifications (GHTF)	Country of Origin	Product Information	
Greiner Bio-One	Bad Haller Straße 32 A-4550 Kremsmünster Austria Phone: +43 7583 6791-0 Fax: +43 7583 6318 E-Mail: office@at.gbo.com	MiniCollect® Tubes	No additive tubes Serum tubes Plasma tubes Serum / Plasma Gel tubes EDTA tubes Glucose tubes Coagulation tubes	.25 ml - 1.0 ml (depends on tube type)	contact manufacturer	contact manufacturer	http://www.gbo.com/en/index_1789.php	
Innovative Medical Technologies Inc	15059 Cedar Street Leawood, KS 66224 Phone: 866.560.1820 Fax: 800.768.2825 Email: support@innovativemedtech.com	Capi-Draw	Serum Gel tubes Bilirubin Serum Gel tubes Lith-Hep tubes Lith-Hep Plasma Gel tubes Sodium Fluoride tubes	200 uL	CE mark	Germany	http://www.innovativemedtech.com/capi-draw.html	
RAM Scientific	Phone: 1.800.535.6734 Phone: 1.914.969.7900 Email: info@ramsci.com	SAFE-T-FILL	EDTA tubes Lithium Heparin tubes Sodium Flouride tubes Serum tubes	125 uL - 300 uL (depends on tube type)	contact manufacturer	contact manufacturer	http://www.ramsci.com/bcoverview.htm	
Sarstedt, Inc.	P O Box 468 Newton, NC 28658-0468 800/257-5101 FAX: (828) 465-4003 E-mail: info@sarstedt.com	Microvette	Serum tubes Plasma / Lithium Heparin tubes Glucose / Floride tubes	200 uL, 300 uL, and 500 uL	contact manufacturer	contact manufacturer	http://www.sarstedt.com/php/main.php?newlanguage=en	
NOTES:								
The price for capillary blood collection equipment is approximately $0.80. This pricing is often dependent upon the volume purchased and may be subject to an order minimum. Additionally this price range does not take into account the costs associated with freight, duty, or clearance. When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer. A request for quote should include the syringe size and needle size as part of the specification.								
GHTF = Global Harmonization Task Force								

ATTACHMENT H
Safe Injection Supplies
Lancets

Manufacturer	Contact Information	Brand Name	Description	Part number and Blade / Needle size	Certifications (GHTF)	Country of Origin	Product Information
Becton Dickinson	One Becton Dr. Franklin Lakes, NJ 07417 Phone: 888/237-2762 Phone: 201/847-6800 Fax: 201/847-6475	BD Microtainer® Contact-Activated Lancet	Activates only when it is positioned and pressed against the skin	366592 - Needle: 30 G x 1.5 mm depth 366593 - Needle: 21 G x 1.8 mm depth 366594 - Blade: 1.5 mm width x 2.0 mm depth	contact manufacturer	contact manufacturer	http://www.bd.com/vacutainer/products/capillary/
		BD Genie Lancet	Permanently retractable blade or needle feature	366582 - Blade Depth 2.0mm and Blade Width 1.5mm 366581- Blade Depth 1.5mm and Blade Width 1.5mm 366580 - Blade Depth 1.0mm and Blade Width 1.5mm 366583 - Needle Depth 2.25mm and 23 gauge needle 366579 - Needle Depth 1.25mm and 28 gauge needle	contact manufacturer	USA	http://www.bd.com/vacutainer/pdfs/genie_lancet_wallchart_VS5422.pdf
Covidien (The Kendall Company)	15 Hampshire Street Mansfield, MA 02048 Phone: 800/962-9888	MONOJECT™ MONOLETTOR™ Safety Lancets	Automatically retracts and locks after puncture	8881602091 - Needle: 21G x 2.4mm depth	contact manufacturer	contact manufacturer	http://www.kendallhealthcare.com/kendallhealthcare/pageBuilder.aspx?topicID=75804&breadcrumbs=0:121623,81034:0,75771:0
Owen Mumford	Brook Hill, Woodstock, Oxford United Kingdom Export Division Tel: +44 1993 812021 Fax: +44 1993 813473 Email: export@owenmumford.co.uk	Unistik 3	Needle point is hidden before use and automatically retracts after use	AT1042 & AT1044 - Needle: 28G AT1002 & AT1004 - Needle: 23G AT1012 & AT1014 - Needle: 21G AT1052, AT1054 - Needle: 18G	contact manufacturer	contact manufacturer	http://www.owenmumford.com/en/range/14/unistik-3.html
Roche Diagnostics	9115 Hague Road Indianapolis, IN 46250 Phone: 317-521-2000	Accu-Chek Safe-T-Pro , Accu-Chek Safe-T-Pro Plus	Permanently retracts into its protective case after use	Safe-T-Pro: 03136752001 - needle 23G Safe-T Pro Plus: 03448622001 - needle 23G; depth settings – 1.3mm, 1.8mm, and 2.3mm	CE mark	Safety Pro - Poland, Safety Plus - US	http://www.poc.roche.com/poc/rewrite/generalContent/en_US/article/POC_general_article_106.htm
Sarstedt, Inc.	P O Box 468 Newton, NC 28658-0468 Phone: 800/257-5101 Fax: (828) 465-4003 E-mail: info@sarstedt.com	Safety Lancet	Lancet safely enclosed in a protective casing before and after blood collection	85.1015.050 - 1.6mm x 28G 85.1016.050 - 1.8mm x 21G 85.1017.050 - 1.8mm x 18G 85.1018.050 - 1.6mm x 1.5mm (blade) 85.1019.050 - 1.2mm x 1.5mm (blade)	CE mark	Poland	http://www.sarstedt.com/php/main.php?newlanguage=en
Smiths Medical	2231 Rutherford Rd Carlsbad, CA 92008 Phone: 800-426-2448 Phone: 760-602-4400 Email: info.cc@smiths-medical.com	Saf-T-Lance Plus® Safety Lancets	Automatic retraction and needle shielded before and after use	1005 - Maximum Flow Blade 1008 - High Flow 18 Gauge. 1014 - Normal Flow 21 Gauge. 1020 - Low Flow 25 Gauge. 1025 - Micro Flow 28 Gauge. 1028 - Pediatric Blade	CE mark	contact manufacturer	http://www.smiths-medical.com/catalog/blood-draw/lancets/safe-t-lance-plus.html

ATTACHMENT H
Safe Injection Supplies
Lancets

Manufacturer	Contact Information	Brand Name	Description	Part number and Blade / Needle size	Certifications (GHTF)	Country of Origin	Product Information
Terumo Medical Corp.	2101 Cottontail Lane Somerset, NJ 08873 800/326-6457 FAX 732/302-3093 E-mail: safety.sharps@medical.com	Capiject® Safety Lancet	Automatic blade or needle retraction styles - the sharp edge is enclosed before and after use	200101 - Blade width 1.5mm and depth 1.0mm 200102 - Blade width 1.5mm and depth 1.5mm 200103 - Blade width 1.5mm and depth 2.0mm 200104 - Needle gauge 23G and depth 2.25mm 200105 - Needle gauge 28G and depth 1.25mm	contact manufacturer	contact manufacturer	http://www.terumotmp.com/ProductDetails.aspx?ApplicationId=4&productId=625
NOTES:							
Prices for lancets range from approximately $0.159 to $0.190. This pricing is often dependent upon the volume purchased and may be subject to an order minimum. Additionally this price range does not take into account the costs associated with freight, duty, or clearance. When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer. A request for quote should include the syringe size and needle size as part of the specification.							
GHTF = Global Harmonization Task Force							

ATTACHMENT I
Safe Injection Supplies
Dental Syringes

Manufacturer	Contact Information	Brand Name	Description	Needle Gauge and Length	Certifications (GHTF)	Country of Origin	Product Information
Milestone Scientific	45 Knightsbridge Road Piscataway, NJ 08854 Toll Free: 800-862-1125 Phone: 973-535-2717 Fax: 973-535-2829 Email: frossi@milestonescientific.com	SafetyWand	Auto-retracting design shields the needle when not in use	contact manufacturer	contact manufacturer	USA	http://www.milestonescientific.com/safetywand.html
Septodont, Inc.	245-C Quigley Blvd New Castle, DE 19720 Phone: 800-872-8305 FAX: 302-328-5653	Safety Plus Injection System	Manually slide the sheath to a locked position, covering the needle	X-short, 0.3 x 10 mm, 30 Gauge x 3/8" Short, 0.3 x 25 mm, 30 Gauge x 1" Short, 0.4 x 25 mm, 27 Gauge x 1" Long, 0.4 x 35 mm, 27 Gauge x 1 3/8"	CE mark	contact manufacturer	http://www.septodont.co.uk/index.php?option=com_content&task=view&id=58&Itemid=40
NOTES:							
Prices for dental syringes is unknown, contact the manufacturer. When contacting a manufacturer, inquiry about the lead time for the order, which also varies per manufacturer. A request for quote should include the syringe size and needle size as part of the specification.							
GHTF = Global Harmonization Task Force							

ATTACHMENT J
Personal Protective Equipment
Gloves for Incinerator Operators

Manufacturer	Contact Information	Product(s)	Specifications	Approximate Cost; Quantity	Order Minimum	Lead Time	Country of Origin	Prequalifications, Registrations, Certifications	Product Literature Included	Comments
ANSELL	200 Schulz Drive Red Bank, NJ 07701 Tel: 1-800-800-0444 www.ansellpro.com	The Duke	Engineered yarns protecting from cuts and abrasions; leather palm and leather thumb crotch providing protection against punctures and moderate heat; excellent grip when wet or dry; launderable	-	-	-	USA	N/A	Yes	
Distributor										
Star Safety	Tel: 1-877-770-9277 www.gssstore.com	Ansell Edmont The Duke SafeKnit CX	Offered in size 9 (large) and size 10 (X-large)	US$14.61; 12+ US$12.52; 48+ US$11.27; 96+ US$10.44; 240+	-	Contact distributor	USA	N/A	-	
ANSELL	200 Schulz Drive Red Bank, NJ 07701 Tel: 1-800-800-0444 www.ansellpro.com	SafeKnit CX	SafeKnit/cotton blend; cut protection; oil grip; protection from intermittent heat up to 300°F; launderable	-	-	-	USA	N/A	Yes	
Distributor										
-	-	-	-	-	-	-	-	-	-	Unable to locate a distributor that ships internationally.
NORTH SAFETY	North Safety Products 2000 Plainfield Pike Cranston, RI 02921 www.northsafety.com	Grip N Kevlar Hot Mill Nitrile Coated Lint Free Gloves (52/7456B)	Kevlar knit design with nitrile coating; cut resistant; protection against intermittent heat up to 400°F; excellent grip; launderable	-	-	-	USA	N/A		
Distributor										
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	North Grip N Kevlar Hot Mill Gloves	Offered in one-size-fits-all (usually large)	US$14.20; 1-23 US$13.00; 24-47 US$12.00; 48+	-	Contact distributor	USA	N/A	-	
PERFECT FIT	85 Innsbruck Drive Buffalo, NY 14227 Tel: 1-800-245-6837 gloveinfo@sperianprotection.com	Tuff-Knit KV	100% Kevlar; protection against cuts, slashes, and abrasions; can withstand temperatures up to 900°F; launderable	-	-	-	USA	N/A	Yes	
Distributor										
Safety Wear	Tel: 1-800-877-3555 www.safety-wear.com	Tuff-Knit 7-cut heavyweight 100% Kelvar gloves with thumb crotch	Offered in womens and mens	Womens: US$9.13 Mens: US$9.36	-	Contact distributor	USA	N/A	-	

ATTACHMENT J
Personal Protective Equipment
Gloves for Incinerator Operators

Manufacturer	Contact Information	Product(s)	Specifications	Approximate Cost; Quantity	Order Minimum	Lead Time	Country of Origin	Prequalifications, Registrations, Certifications	Product Literature Included	Comments
PERFECT FIT	85 Innsbruck Drive Buffalo, NY 14227 Tel: 1-800-245-6837 gloveinfo@sperianprotection.com	Guard Dog and Junk Yard Dog	DuPont Kevlar fiber; cut resistant; leather palm; grip in oily and wet applications; excellent heat and flame resistance; dry cleaning recommended because of the leather palms	-	-	-	USA	N/A	Yes	
Distributors										
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	Perfect Fit GuardDog	Offered in womens, mens, and jumbo	Womens: US$14.80 Mens: US$15.10 Jumbo: US$15.60	-	Contact distributor	USA	N/A	-	
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	Perfect Fit Junk Yard Dog	Offered in one-size-fits-all (usually large)	US$14.70; 1-11 US$13.80; 12+	-	Contact distributor	USA	N/A	-	
Safety Wear	Tel: 1-800-877-3555 www.safety-wear.com	Perfect Fit Junk Yard Dog	Offered in mens	US$14.73	12	Contact distributor	USA	N/A	-	

Note 1: Costs were obtained from the distributor websites and may vary depending on the quantity and date of purchase. All costs are x-factory and do not include freight or duty.
Note 2: There are no NIOSH standards for gloves, therefore manufacturers in the United States do not have to certifications.
Note 3: There are many quality protective gloves on the market. The above protective gloves are provided as an example only.

ATTACHMENT K
Personal Protective Equipment
Protective Respirators (Dust Masks) for Incinerator Operators

Manufacturer	Contact Information	Product(s)	Specifications	Approximate Cost; Quantity	Order Minimum	Lead Time	Country of Origin	Prequalifications, Registrations, Certifications	Product Literature Included	Comments
MOLDEX	10111 W. Jefferson Blvd. Culver City, CA 90232 Tel: 1-800-421-0668 www.moldex.com	8000 Series: 8941, 8942, 8943 Face piece assembled with P100 disk #8940 and disk/filter holder #8900	Reusable half-face mask; 100% PVC free	-	-	-	USA	US: NIOSH approved	Yes	
Distributors										
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	Moldex 8000 series half-mask respirator	Offered in small, medium, and large	US$13.70; 1–9 US$12.40; 10+	-	Contact distributor	USA	US: NIOSH approved	-	Total cost = US$24.64
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	Moldex 8000 series half-mask respirator P100 cartridge	1 box contains 10 cartridges	US$54.70	1 Box	Contact distributor	USA	US: NIOSH approved	-	
Professional Equipment	Tel: 1-800-334-9291 www.professional equipment.com	Moldex half-face particulate P100	Offered in small, medium, and large	US$19.95	-	Contact distributor	USA	US: NIOSH approved	-	Total cost = US$30.34
Professional Equipment	Tel: 1-800-334-9291 www.professional equipment.com	Moldex P100 particulate cartridge	1 box contains 10 cartridges	US$51.95; 1 US$49.35; 2-11 US$47.35; 10+	1 Box	Contact distributor	USA	US: NIOSH approved	-	
MSA	PO Box 426 Pittsburgh, PA 15230 Tel: 1-800-MSA-2222 www.msanorthamerica.com	Advantage 200 LS; GMA P100 cartridge	Reusable half-face mask; thermoplastic rubber; inhalation/exhalation valves	-	-	-	USA	US: NIOSH approved	Yes	
Distributors										
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	MSA advantage 200 low-maintenance half-mask respirator	Offered in small, medium, and large	US$17.70	-	Contact distributor	USA	US: NIOSH approved	-	Total cost = US$26.80
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	MSA P100 filter cartridge	1 pack contains 2 cartridges	US$9.10; 1-11 US$8.40; 12+	1 Pack	Contact distributor	USA	US: NIOSH approved	-	
Professional Equipment	Tel: 1-800-334-9291 www.professionalequipment.com	MSA advantage 200 LS half-face respirator	Offered in small, medium, and large	US$14.95	-	Contact distributor	USA	US: NIOSH approved	-	Professional Equipment does not carry P100 filter cartridge; need to purchase them from Lab Safety Supply.
NORTH SAFETY	2000 Plainfield Pike Cranston, RI 02921 www.northsafety.com	5500 series low-maintenance half-mask	Reusable, half-face non-allergenic elastomer mask; elastic strap	-	-	-	USA	US: NIOSH approved	Yes	
Distributor										
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	North half-mask low-maintenance respirator	Offered in small, medium, and large	US$13.30; 1-9 US$12.00; 10+	-	Contact distributor	USA	US: NIOSH approved	-	Total cost = US$20.80
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	North P100 filter cartridge	1 pack contains 2 cartridges	US$7.50; 1-11 US$7.00; 12+	1 Pack	Contact distributor	USA	US: NIOSH approved	-	
Professional Equipment	Tel: 1-800-334-9291 www.professional equipment.com	North safety 5500 series half-mask	Offered in small, medium, and large	US$12.95	-	Contact distributor	USA	US: NIOSH approved	-	Total cost = US$29.90
Professional Equipment	Tel: 1-800-334-9291 www.professional equipment.com	North safety defender multi-purpose cartridge and P100 filter	1 pack contains 2 cartridges	US$16.95; 1-11 US$16.35; 12-71	-	Contact distributor	USA	US: NIOSH approved	-	

ATTACHMENT K
Personal Protective Equipment
Protective Respirators (Dust Masks) for Incinerator Operators

Manufacturer	Contact Information	Product(s)	Specifications	Approximate Cost; Quantity	Order Minimum	Lead Time	Country of Origin	Prequalifications, Registrations, Certifications	Product Literature Included	Comments
SURVIVAIR	900 Douglas Pike Smithfield, RI 02917 Tel: 619-671-1473 www.survivair.com	Premier half-mask respirator T-series bayonet	Reusable, half-face silicone mask; bayonet cartridge mount; elastic strap	-	-	-	USA	US: NIOSH approved	Yes	
Distributor										
Gempler's	Tel: 1-800-382-8473 www.gemplers.com	Survivair premier half-mask respirator	Offered in small, medium (fits 80% of men), or large	US$28.50; 1-3 US$26.10; 4+	-	Contact distributor	USA	US: NIOSH approved	-	Gempler's does not carry P100 cartridge; need to purchase them from Lab Safety Supply.
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	Survivair premier series respirators	Offered in small, medium, and large	US$24.80; 1-4 US$22.90; 5-9 US$21.70; 10+	-	Contact distributor	USA	US: NIOSH approved	-	Total cost = US$45.65
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	Survivair T-series (bayonet) cartridges, multi contaminant cartridge/P100 filter	1 pack contains 4 filters	US$41.70; 1-11 US$37.60; 12-23 US$35.40; 24-47	1 Pack	Contact distributor	USA	US: NIOSH approved	-	
3M	3M Corporate Headquarters 3M Center St. Paul, MN 55144-1000 Tel: 1-888-3M-HELPS www.3m.com	6000 series half-mask respirator 6100 (s), 6200 (m), 6300 (l)	Reusable, half-face silicone mask; bayonet cartridge mount; temp not to exceed 120°F; includes exhalation valve; synthetic polyisoprene elastic strap in a cotton/polyester braid	-	-	-	USA	US: NIOSH approved European: Face piece—EN140:1998 Filter—EN143:2000	Yes	
Distributor										
Gempler's	Tel: 1-800-382-8473 www.gemplers.com	3M 6000 series half-mask respirator	Offered in small, medium, and large:small fits women and smaller facial features; medium fits 80% of men	US$12.00; 1-2 US$10.90; 3+	-	Contact distributor	USA	-	-	Total cost = US$34.35
Gempler's	Tel: 1-800-382-8473 www.gemplers.com	3M P100 acid gas/organic vapor cartridge	2 cartridges per order	US$22.35	Pair	Contact distributor	-	-	-	
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	3M 6000 series low-maintenance half-mask respirator	Offered in small, medium, and large	US$12.30	-	Contact distributor	USA	US: NIOSH approved	-	Total cost = US$34.30
Lab Safety Supply	Tel: 1-800-356-0783 www.lss.com	3M organic vapor/acid gases cartridge with P100 filters	1 pack contains 2 cartridges	US$22.00	1 Pack	Contact distributor	USA	US: NIOSH approved	-	

Note 1: Costs were obtained from the distributor websites and may vary depending on the quantity and date of purchase. All costs are x-factory and do not include freight or duty.
Note 2: Masks and filters/cartridges are sold separately.

ATTACHMENT L

European and Australian/New Zealand Glove Standards

Did you know that there is a range of Australian & New Zealand Standards which cover a number of different applications and the general fit and quality of gloves for industrial applications?

These standards are known as the 'AS/NZS 2161 Occupational Protective Gloves' Standards. The Australian/New Zealand Glove Standards have been based on the European Standards to ensure gloves for industrial applications meet appropriate quality requirements. Additionally the Standards also provide the performance characteristics of a particular glove in a clear and easy to understand manner.

The European and Australian/New Zealand Standards are made up of a number of different Standards. Each Standard reflects the different requirements of certain gloves for a given application. The individual Standards that make up AS/NZS are listed below:

AS/NZS 2161.1:2000
Occupational Protective Gloves Part 1: Selection, Use and Maintenance

AS/NZS 2161.2:1998
Occupational Protective Gloves Part 2: General Requirements
(Based on European Standard EN 420:1994)

AS/NZS 2161.3:1998
Occupational Protective Gloves Part 3: Protection Against Mechanical Risks
(Based on European Standard EN 388:1994)

AS/NZS 2161.4:1999
Occupational Protective Gloves Part 3: Protection Against Thermal Risks (Heat & Fire)
(Based on European Standard EN 407:1994)

AS/NZS 2161.5:1998
Occupational Protective Gloves Part 3: Protection Against Cold
(Based on European Standard EN 511:1994)

AS/NZS 2161 7.1:1998
Occupational Protective Gloves Part 3: Protection Against Cuts and Stabs by Hand Knives Chainmail Gloves and Arm Guards
(Based on European Standard EN 1082-1:1997)

Part 1 Occupational Protective Gloves: Selection, Use and Maintenance

What does AS/NZS 2161.1:2000 Occupational Protective Gloves Part 1: Selection, Use and Maintenance cover?

This standard provides recommendations on ensuring that gloves intended for industrial or occupational use are selected and maintained in a manner that will provide workers with adequate levels of protection.

Put simply, the standard gives guidance on the following:

HAZARD IDENTIFICATION

Incorporating a hand and arm protection program in the workplace which:

- identifies the hazards and risks;
- tries to control those risks;
- ensures the right gloves are selected;
- involves worker training on use and maintenance and
- ensures correct disposal of the gloves.

GLOVE SELECTION

There are many gloves on the market, and workers should always consult specialist advice when choosing the most appropriate glove for the application. The standard provides a basic process for selecting protective gloves:

- identify the hazards;
- identify the level of dexterity;
- select the right glove material;
- select the most appropriate style and fit for the user and application;
- check with the workers to see if the glove is acceptable;
- ensure a product data sheet is available for the gloves;
- consider any cleaning and maintenance for the gloves; and
- consider and implement a safe disposal method of used gloves.

USE AND MAINTENANCE OF GLOVES

Whether the gloves are being used correctly and how they should be looked after?
Considerations include:

- make sure hands are clean before and after using the glove;
- check with specialist advice to see if the gloves can safely be used with different chemicals;
- make sure workers are trained and supervised and there is a good supply of glove sizes available;
- check gloves before, during and after use for any defects; and
- consider the correct storage and disposal requirements of the gloves.

Remember, when the right procedure is followed in selecting gloves, the glove will perform better, last longer and provide the right level of protection.

Occupational Protective Gloves Part 2: General Requirements

What does AS/NZS 2161.2:1998 Occupational Protective Gloves Part 2: General Requirements cover?

This standard defines the general requirements for protective gloves. It also provides a guideline of what to look for in a quality glove. Factors to include:

- ergonomic fit – is the glove designed for different hand sizes?;
- glove construction;
- whether the glove provides protection without harm to the user;
- cleaning requirements;
- comfort and efficiency; and
- size labelling, markings and information about the glove.

Put simply, the Standard requires that:

The glove design and construction is *suitable for its intended use*, any seams or stitching in the glove construction (for example cotton, leather gloves) do not result in a significant decrease in product performance.

When the glove is used it will not harm the health of the user. This may include rough edges, gaps, or faults in the glove.

The glove sizing conforms to set specifications with respect to hand circumference. For example a 'size 9' glove should suit a persons hand with a hand circumference of 229mm.

Additionally, minimum glove lengths are specified for each size.
For example a 'size 9' glove must be at least 250mm long. Gloves must be generally marked with a trade mark or other identification of the manufacturer / representative. The product code or commercial name and size must also be stated.

Packaging should also list where to find out more information about the glove. Such as; uses & limitations and the size range available. Packaging should also provide information on pictograms denoting performance levels against different Standards as appropriate. Information should also be available on the use, storage and care of the gloves and any known substances that can cause allergies.

Where the words "For Minimal Risk Only" appear, this means the glove is intended to protect the user against light duty applications. For example, weak cleaning solutions, light abrasive materials or where there is no chance of permanent damage to the worker.

The Australian and New Zealand Standards are designed to provide users with a clear set of guidelines for gloves intended for use in the workplace.

Occupational Protective Gloves Part 3: Protection Against Mechanical Risks

What does AS/NZS 2161.3:1998 (EN 388:1994) Protection Against Mechanical Risk cover ?

This standard is applicable to all kinds of gloves that provide protection against mechanical hazards. A mechanical hazard is one that can be caused by abrasion, blade cuts, tearing and puncturing among other things. This Standard may also be used to determine the impact cut resistance and anti-static nature of the glove.

The four basic performance tests that are mentioned in this Standard are:
Abrasion resistance
How well can the material of the glove resist exposure to repeated abrasion?

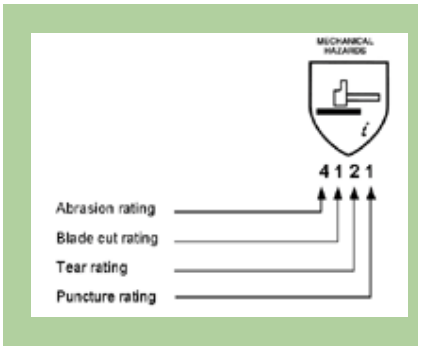
Blade cut resistance
How good is the glove's resistance to cutting objects?

Tear resistance
What force is needed to tear a pre-cut hole in the material of the glove?

Puncture resistance
What force is needed to puncture the palm of the glove with a calibrated spike?

Further optional testing of impact cut resistance and anti-static (volume resistivity) performance may also be performed.

What do the pictures mean?
The Mechanical Hazards symbol shows how the glove rates against each of these 4 basic tests (above) and records the results as performance ratings. The higher the rating, the better the glove is, with respect to the performance tests.
The 'i' symbol in the picture means that the ratings are for information only.



In this example the glove with a rating of 4 1 2 1 has excellent abrasion resistance (4), but a low cut resistance (1), good tear resistance (2) and a low puncture resistance (1).

The following table relates to the values from the laboratory testing.

Test	Level 1	Level 2	Level 3	Level 4	Level 5
Abrasion Resistance (# of cycles)	100	500	2,000	8,000	-
Blade Cut Resistance (Index)	1.2	2.5	5.0	10.0	20.0
Tear Resistance (Newton)	10	25	50	75	-
Puncture Resistance (Newton)	20	60	100	150	-

As you will see, the higher the rating the better protection the glove offers.

Don't forget, all tests are performed in independently controlled laboratory conditions, and the ratings are for information and comparison purposes only. This allows you to compare 2 gloves and find out which one is better suited for your application.

NIOSH

42 CFR Part 84
Respiratory Protective Devices

SUMMARY: This final rule was made available to the public at the Government Printing Office in Washington, DC, on June 2, 1995. It is scheduled for publication in the Federal Register on June 8, 1995, in Part II of that issue. This rule addresses NIOSH and the Department of Labor/Mine Safety and Health Administration (MSHA) certification requirements for respiratory protective devices. Specifically, the rule replaces MSHA regulations at 30 CFR part 11 with new public health regulations at 42 CFR part 84, while also upgrading testing requirements for particulate filters. Concurrently with publication by NIOSH of this new rule, MSHA published a final rule to remove existing regulations at 30 CFR part 11, which are made obsolete by this final rule. NIOSH will now have exclusive authority for testing and certification of respirators with the exception of certain mine emergency devices, which will continue to be jointly certified by NIOSH and MSHA.

The certification of air-purifying respirators under the final rule will enable respirator users to select from a broader range of certified respirators. All of these new respirators will meet the performance criteria recommended by CDC for respiratory devices used in health-care settings for protection against *Mycobacterium tuberculosis* (Mtb), the infectious agent that causes tuberculosis (TB). The CDC published "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994", in the Federal Register (59 FR 54242) and MMWR (Volume 43, No. RR-13) on October 28, 1994. All nine classes of air-purifying, particulate respirators to be certified under the provisions of the new particulate filter tests exceed the performance recommendations contained in the CDC Guidelines. Several of these new classes of air-purifying, particulate respirators are expected to be less expensive than respirators with HEPA filters.

This action is the first of a series of modules that will incrementally upgrade current respirator approval standards. This modular approach will allow improvements to be implemented on a safety and health priority basis as well as facilitate adaptation to new requirements by the manufacturers and users of respirators. It will also expedite the incorporation of technological advancements and will allow for expeditious response to emerging hazards.

Except for the particulate-filter standards, most of the existing regulations are incorporated into the new 42 CFR part 84 without change. The revised testing standards for particulate filters will significantly improve the effectiveness of air-purifying filters in removing toxic particulates from the ambient air. These changes are consistent with two decades of advances in respiratory protection technology.

Under the new particulate filter tests, NIOSH will certify three classes of filters, N-, R-, and P-series, with three levels of filter efficiency, 95%, 99%, and 99.97%, in each class. All filter tests will employ the most penetrating aerosol size, 0.3 μm aerodynamic mass median diameter. The N-series will be tested against a mildly degrading aerosol of sodium chloride (NaCl). The R- and P-series filters will be tested against a highly degrading aerosol of dioctylphthalate (DOP):

Filter Designation	Minimum Efficiency	Test Agent	Maximum Test Challenge Loading
N100	99.97%	NaCl	200 mg filter loading
N99	99%	NaCl	200 mg filter loading
N95	95%	NaCl	200 mg filter loading
R100	99.97%	DOP	200 mg filter loading
R99	99%	DOP	200 mg filter loading

R95	95%	DOP	200 mg filter loading
P100	99.97%	DOP	Maximum filter degradation
P99	99%	DOP	Maximum filter degradation
P95	95%	DOP	Maximum filter degradation

Tested to a specified maximum loading level (200 mg), the N- and R-series will be certified with the recognition that in some settings time-use limitations will apply. A single shift time limitation, for example, may be appropriate. In addition to possible time-use restrictions, the N-series filters should be restricted to use in those workplaces free of oil or other severely degrading aerosols. The R-series filters would not have similar aerosol-use restrictions. The P-series filters will be tested with DOP until no further decrease in filter efficiency is observed. The P-series filters have neither aerosol-use nor time-use limitations. As for any filter, service time will be limited by considerations of hygiene and increased breathing resistance due to filter loading.

The final rule differs from the proposal (59 FR 26850) in eight ways. These changes are summarized as follows:

PROPOSAL	FINAL RULE
2 categories of particulate filters (Solid; Solid and Liquid)	3 categories of particulate filters (N-, R-, and P-series)
Filter efficiency tests applied to all air-purifying particulate filters. Filters respirators module.	Filter efficiency tests apply only to air-purifying particulate filters for non-powered respirators. Filters for powered air-purifying respirators will be addressed in another
Inhalation resistance maximum at 30 mm; exhalation resistance maximum at 20 mm.	Inhalation resistance maximum at 35 mm; exhalation resistance maximum at 25 mm.
Isoamyl acetate tightness test for particulate respirators was included.	Isoamyl acetate tightness test was eliminated from the certification procedures.
Certification of filters was based on from 20 statistical evaluation of results from 30 filters tested.	Pass/Fail test based on results filters tested. All must pass.
Pending Part 11 applications would be will processed for six months, and no new applications Part 11 applications accepted after the effective date of effective date of Part 84. considered for approval under Part 84.	All pending Part 11 applications be processed. All new received after the Part 84 will be .
Approval holders allowed to manufacture manufacture and sell Part 11 filters as approved approved devices for 2 years from the effective effective date of Part 84.	Approval holders allowed to and sell Part 11 filters as devices for 3 years from the date of Part 84.
No provisions were included for the for the continued issuance of extensions of 30 existing 30 CFR Part 11 approvals.	A new subpart KK has been added issuance of extensions of existing CFR Part 11 approvals to address

there is a demonstrated safety or health need during the 3-year transition period and for the approval of PAPRs until respirator non-conformances when addressed in a later module.

EFFECTIVE DATE: This final rule is effective on July 10, 1995

FOR FURTHER INFORMATION CONTACT: Richard W. Metzler, Chief, Certification and Quality Assurance Branch, Division of Safety Research, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888. The telephone number is (304) 285-5907. Copies of this final rule can be downloaded from the NIOSH World Wide Web page (http://www.cdc.gov/niosh/homepage.html) or may be obtained by calling the NIOSH toll-free information number (1-800-35-NIOSH, option 5, 9:00 am - 4:00 pm, ET). Arrangements have also been made for this final rule to be listed on the electronic bulletin boards of the Government Printing Office and of the Department of Labor; the telephone numbers are (202) 512-1387 and (202) 219-4784, respectively.

The HHS Press Release announcing the publication of the final rule is also available.

The HHS Press Release announcing NIOSH certified respirators is also available.

Go back to the NIOSH Home Page or to the CDC Home Page

NIOSH Federal Respiratory Regulations 42 CFR Part 84

The NIOSH standard, 42 CFR Part 84, is available to the public on NIOSH website. Due to the size of the standard only the section headers are listed below. To access the detail of each section of 42 CFR 84, access the following website: http://www.access.gpo.gov/nara/cfr/waisidx_04/42cfr84_04.html.

Title 42--Public Health

CHAPTER I--PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 84--APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

84.96 Service time test; closed-circuit apparatus.

84.97 Test for carbon dioxide in inspired gas; open- and closed-circuit apparatus; maximum allowable limits.

84.98 Tests during low temperature operation.

84.99 Man tests; testing conditions; general requirements.

84.100 Man tests 1, 2, 3, and 4; requirements.

84.101 Man test 5; requirements.

84.102 Man test 6; requirements.

84.103 Man tests; performance requirements.

84.104 Gas tightness test; minimum requirements.

84.110 Gas masks; description.

84.111 Gas masks; required components.

84.112 Canisters and cartridges in parallel; resistance requirements.

84.113 Canisters and cartridges; color and markings; requirements.

84.114 Filters used with canisters and cartridges; location; replacement.

84.115 Breathing tubes; minimum requirements.

84.116 Harnesses; installation and construction; minimum requirements.

84.117 Gas mask containers; minimum requirements.

84.118 Half-mask facepieces, full facepieces, and mouthpieces; fit; minimum requirements.

84.119 Facepieces; eyepieces; minimum requirements.

84.120 Inhalation and exhalation valves; minimum requirements.

84.121 Head harnesses; minimum requirements.

84.122 Breathing resistance test; minimum requirements.

84.123 Exhalation valve leakage test.

84.124 Facepiece tests; minimum requirements.

84.125 Particulate tests; canisters containing particulate filters; minimum requirements.

84.126 Canister bench tests; minimum requirements.

84.130 Supplied-air respirators; description.

84.131 Supplied-air respirators; required components.

84.132 Breathing tubes; minimum requirements.

84.133 Harnesses; installation and construction; minimum requirements.

84.134 Respirator containers; minimum requirements.

84.135 Half-mask facepieces, full facepieces, hoods, and helmets; fit; minimum requirements.

84.136 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

84.137 Inhalation and exhalation valves; check valves; minimum requirements.

84.138 Head harnesses; minimum requirements.

84.139 Head and neck protection; supplied-air respirators; minimum requirements.

84.140 Air velocity and noise levels; hoods and helmets; minimum requirements.

84.141 Breathing gas; minimum requirements.

84.142 Air supply source; hand-operated or motor driven air blowers; Type A supplied-air respirators; minimum requirements.

84.143 Terminal fittings or chambers; Type B supplied-air respirators; minimum requirements.

84.144 Hand-operated blower test; minimum requirements.

84.145 Motor-operated blower test; minimum requirements.

84.146 Method of measuring the power and torque required to operate blowers.

84.147 Type B supplied-air respirator; minimum requirements.

84.148 Type C supplied-air respirator, continuous flow class; minimum requirements.

84.149 Type C supplied-air respirator, demand and pressure demand class; minimum requirements.

84.150 Air-supply line tests; minimum requirements.

84.151 Harness test; minimum requirements.

84.152 Breathing tube test; minimum requirements.

84.153 Airflow resistance test, Type A and Type AE supplied-air respirators; minimum requirements.

84.154 Airflow resistance test; Type B and Type BE supplied-air respirators; minimum requirements.

84.155 Airflow resistance test; Type C supplied-air respirator, continuous flow class and Type CE supplied-air respirator; minimum requirements.

84.156 Airflow resistance test; Type C supplied-air respirator, demand class; minimum requirements.

84.157 Airflow resistance test; Type C supplied-air respirator, pressure-demand class; minimum requirements.

84.158 Exhalation valve leakage test.

84.159 Man tests for gases and vapors; supplied-air respirators; general performance requirements.

84.160 Man test for gases and vapors; Type A and Type AE respirators; test requirements.

84.161 Man test for gases and vapors; Type B and Type BE respirators; test requirements.

84.162 Man test for gases and vapors; Type C respirators, continuous-flow class and Type CE supplied-air respirators; test requirements.

84.163 Man test for gases and vapors; Type C supplied-air respirators, demand and pressure-demand classes; test requirements.

84.170 Non-powered air-purifying particulate respirators; description.

84.171 Non-powered air-purifying particulate respirators; required components.

84.172 Breathing tubes; minimum requirements.

84.173 Harnesses; installation and construction; minimum requirements.

84.174 Respirator containers; minimum requirements.

84.175 Half-mask facepieces, full facepieces, hoods, helmets, and mouthpieces; fit; minimum requirements.

84.176 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

84.177 Inhalation and exhalation valves; minimum requirements.

84.178 Head harnesses; minimum requirements.

84.179 Non-powered air-purifying particulate respirators; filter identification.

84.180 Airflow resistance tests.

84.181 Non-powered air-purifying particulate filter efficiency level determination.

84.182 Exhalation valve leakage test; minimum requirements.

84.190 Chemical cartridge respirators: description.

84.191 Chemical cartridge respirators; required components.

84.192 Cartridges in parallel; resistance requirements.

84.193 Cartridges; color and markings; requirements.

84.194 Filters used with chemical cartridges; location; replacement.

84.195 Breathing tubes; minimum requirements.

84.196 Harnesses; installation and construction; minimum requirements.

84.197 Respirator containers; minimum requirements.

84.198 Half-mask facepieces, full facepieces, mouthpieces, hoods, and helmets; fit; minimum requirements.

84.199 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

84.200 Inhalation and exhalation valves; minimum requirements.

84.201 Head harnesses; minimum requirements.

84.202 Air velocity and noise levels; hoods and helmets; minimum requirements.

84.203 Breathing resistance test; minimum requirements.

84.204 Exhalation valve leakage test; minimum requirements.

84.205 Facepiece test; minimum requirements.

84.206 Particulate tests; respirators with filters; minimum requirements; general.

84.207 Bench tests; gas and vapor tests; minimum requirements; general.

84.250 Vinyl chloride respirators; description.

84.251 Required components.

84.252 Gas masks; requirements and tests.

84.253 Chemical-cartridge respirators; requirements and tests.

84.254 Powered air-purifying respirators; requirements and tests.

84.255 Requirements for end-of-service-life indicator.

84.256 Quality control requirements.

84.257 Labeling requirements.

84.258 Fees.

84.1100 Scope and effective dates.

84.1101 Definitions.

84.1102 Examination, inspection and testing of complete respirator assemblies; fees.

84.1103 Approval labels and markings; approval of contents; use.

84.1130 Respirators; description.

84.1131 Respirators; required components.

84.1132 Breathing tubes; minimum requirements.

84.1133 Harnesses; installation and construction; minimum requirements.

84.1134 Respirator containers; minimum requirements.

84.1135 Half-mask facepieces, full facepieces, hoods, helmets, and mouthpieces; fit; minimum requirements.

84.1136 Facepieces, hoods, and helmets; eyepieces; minimum requirements.

84.1137 Inhalation and exhalation valves; minimum requirements.

84.1138 Head harnesses; minimum requirements.

84.1139 Air velocity and noise levels; hoods and helmets; minimum requirements.

84.1140 Dust, fume, and mist respirators; performance requirements; general.

84.1141 Isoamyl acetate tightness test; dust, fume, and mist respirators designed for respiratory protection against fumes of various metals having an air contamination level not less than 0.05 milligram per cubic meter; minimum requirements.

84.1142 Isoamyl acetate tightness test; respirators designed for respiratory protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter, or against radionuclides; minimum requirements.

84.1143 Dust, fume, and mist air-purifying filter tests; performance requirements; general.

84.1144 Silica dust test for dust, fume, and mist respirators; single-use or reusable filters; minimum requirements.

84.1145 Silica dust test; non-powered single-use dust respirators; minimum requirements.

84.1146 Lead fume test for dust, fume, and mist respirators; minimum requirements.

84.1147 Silica mist test for dust, fume, and mist respirators; minimum requirements.

84.1148 Tests for respirators designed for respiratory protection against more than one type of dispersoid; minimum requirements.

84.1149 Airflow resistance tests; all dust, fume, and mist respirators; minimum requirements.

84.1150 Exhalation valve leakage test; minimum requirements.

84.1151 DOP filter test; respirators designed as respiratory protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter and against radionuclides; minimum requirements.

84.1152 Silica dust loading test; respirators designed as protection against dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter and against radionuclides; minimum requirements.

84.1153 Dust, fume, mist, and smoke tests; canister bench tests; gas masks canisters containing filters; minimum requirements.

84.1154 Canister and cartridge requirements.

84.1155 Filters used with canisters and cartridges; location; replacement.

84.1156 Pesticide respirators; performance requirements; general.

84.1157 Chemical cartridge respirators with particulate filters; performance requirements; general.

84.1158 Dust, fume, and mist tests; respirators with filters; minimum requirements; general.