SECTION A:

DESIGN CRITERIA AND PERFORMANCE SPECIFICATION FOR SHARPS SAFETY BOXES AND INCINERATOR CONTAINERS

DESIGN CRITERIA

1. NEED
To collect at the point of use and safely contain used disposable or auto-disable syringes with or without needles, in a disposable and readily transportable recipient which can be incinerated or otherwise destroyed in approved devises and according to approved procedures.

2. APPROACH
A puncture proof, impermeable box, designed to prevent access to its contents, for the safe and convenient collection, temporary storage and disposal of used disposable and auto disable syringes and needles and other contaminated sharps.

3. TARGETED PERFORMANCE CRITERIA
   □ Purpose
The purpose of the box or container is to safe guard health workers from risk of contamination from needle stick or other diseases communicated from direct contact with sharp infectious waste placed in safety boxes or incinerator containers.
   □ Functionality
Safety boxes and incinerator containers remain functional during their entire period of usage (i.e., they are durable, closable, leak resistant on their sides and bottom, and puncture resistant until final disposal). More specifically:
   - They are sufficient thickness or of construction design to be durable, leak resistant, and puncture resistant under normal use and stresses imposed during storage, handling, installation, use, closure, and transport within the user facility before final disposal. Durability and puncture resistance remains unaffected by specified variation in temperatures during storage and use.
   - Material is resistant to chemical or liquid permeation or degradation, tearing, abrasion, and laceration.
   - Closure mechanisms are designed to minimize exposure to contents and injury to the hand during engagement of the closure mechanism or during transport within the user facility before final disposal. Once activated, the final closure mechanism of a safety boxes and incinerator container is resistant to manual opening.
   - Is stable during use as described in product labelling.
If transported in knock down or folded form, they are simple to assemble, with clear, readily visible, graphic instructions for assembly indicated on the box or container.

They are convenient to handle, carry, and stack with minimal risk of needle stick or contamination from infectious waste contained within.

### Accessibility
Containers are accessible to workers who use, maintain, or dispose of sharp devices. Convenient placement is also to be considered, along with portability of containers within the work place, if necessary.

- Safety boxes and incinerator containers are designed to permit safe disposal of used syringes and needles and are simple and easy to operate. The disposal opening prevent spills of the contents (objects or liquid) while in use in the intended upright position, during the closure and sealing process, and during transportation within the user facility before final disposal. The disposal opening is identifiable and accessible by the user and facilitates one-handed disposal.

- Handles, if present, are sufficiently sturdy to avoid breaking when the Safety boxes and incinerator container is in use or during transportation before final disposal. If handles are present, they are placed so that the user's hands are not close to the disposal opening when the handles are used, and they are positioned above the full-fill level.

- Proper Safety boxes and incinerator container location and placement ensure that containers are readily visible and within easy horizontal reach of the user. Where containers are fixed to walls or other permanent sites, the vertical height allows the worker to view the opening or access of the container.

- Safety boxes and incinerator containers are placed within arm's reach and below eye level at their point of use.

### Visibility
The following features are plainly visible to the workers who use Safety boxes and/or incinerator containers:

- The box or container, the degree to which it is full, the proper warning labels, and the colour coding of the container.

- the disposal opening or access mechanism.

- Hazard warning labelling. Such labels and device colours imply danger. Either the device colour or a warning label is visible to the user to warn of a potential hazard before syringes or needles are placed in the container.
Accommodation

Boxes or containers should be accommodating and convenient for users. Accommodation also includes ease of storage, assembly, and operation. Elements of accommodation comprise:

- Container design permits one-handed disposal.
- Special aesthetic, operational, or safety features do not hide or impede free access to the device, the inlet, or the closure process.
- Users are able to assemble containers easily, if required.
- Mounting systems are safe, durable, stable, cleanable, and (where appropriate) lockable.
- Placement in and removal from mounting systems is simple and uncomplicated and does not compromise safety and security.
- Containers are designed so that they are simple to use.
- User training information is provided by manufacturers.
SECTION B:

PERFORMANCE SPECIFICATIONS FOR SHARPS SAFETY BOX AND INCINERATOR CONTAINERS FOR HEALTH WASTE MANAGEMENT

Specification reference: <PQS category>/<unique reference>
Product verification protocol: <PQS category>/<unique reference>
Date of origin: <dd.mm.yy>
Date of last revision: <dd.mm.yy>

Contents: <list the specification content down to level 1.1.1>

1. Scope:

Design specifications for sharps safety box and incinerator containers required to safely and efficiently contain, store, transport and dispose of used disposable and auto-disable syringes and needles.

2. Normative references:


b. Selecting, Evaluating and Using Sharps Disposal Containers, DHHS (NIOSH) Publication No. 97-111


3. Terms and definitions:

   1. Sharp: Any type or form of medical waste which through direct contact with health workers, waste handling/processing personnel or the public at large may penetrate the skin if brought into direct contact.
   2. Sharps Safety Box: A container to safely hold sharps.
   3. Incinerator Container: A container to safely hold and dispose of sharps excluding PVC or other toxic materials by direct combustion of the container.

4. Requirements

4.1 General:
Poorly managed sharps waste expose health workers and the community to injuries and infection. The efficient, safe and environmentally-friendly management of sharps waste ensures that single-use syringes and needles are contained and minimize the risks of needle-stick injuries. The management of sharps waste must be considered within the broader context of health care waste management.

4.2 Performance:

Type of use:

- containment of contaminated syringes and needles at point of use;
- containment during handling and transportation to point of final disposal
- containment during temporary storage
➢ a disposal or incineration container.
➢ A combustion chamber (if applicable)

**Net capacity:**
1Ltr to 20Ltr useful storage volume

**Combustion container: (Applicable to incinerator containers only)**
Container shall allow for syringes to completely burn without spillage of contents.

**Distribution container:**
Container should minimize space required during initial shipment, and must accept no less than 20 syringes of 5ml size with attached needles per ltr of useable storage capacity when syringes are dropped in randomly.

**Handling:**
Able to be carried in one hand without spillage of contents and without risk of needle stick.

4.3  

**Environmental requirements:**

**Resistance to piercing:**

➢ Container shall accept 20 x 0.5 ml syringes, 25 mm needles per ltr capacity. Needles shall not penetrate container walls when filled up to the filling line, but at least with 20 x 0.5 ml syringes per ltr capacity with unsheathed fixed needles and dropped according to standard drop test. No syringes to be spilled from the container during test (*see BS 7320:1990 appendix C*).

➢ The average of forces needed to penetrate samples taken from each position shall be not less than 15 N, and the force required to penetrate any one sample from wherever taken shall not be less than 12.5 N.

**Ignition: (Applicable to Incinerator containers only)**
A means of IATA approved ignition shall be supplied with the container so that no other energy source is required. Container to comply with IATA rules so that it can be shipped with no restrictions

**Tamper-proofing:**
When contaminated syringes are dropped into the container, it shall remain sufficiently sealed so as to prevent a hand from entering. Syringes should not protrude from the container when the box contains 20 syringes per ltr of usable capacity. The container must be capable of being closed.

**Water resistance:**
Able to withstand 48 hours at 43°C at 90% relative humidity in 5 mm of water, without spilling any part of its load.

**Temperature resistance:**
Able to resist temperatures of up to 170°C for periods up to 30 minutes without spilling any part of its load.
4.4 *Physical characteristics:*

Safety boxes and incinerator containers should be of sufficient size to accommodate the largest sharp used at the workstation it serves. Containers should also be shaped to accommodate the particular type of sharp that requires disposal. Safety boxes and incinerator containers should also be of sufficient size to accommodate the volume of sharps typically generated at the site between waste collection operations.

4.5 *Interface requirements:*

External dimensions of safety boxes and incinerator containers for a given volumetric capacity should not exceed those adopted by incinerator manufacturers in hopper loading mechanisms.

4.6 *Human factors:*

- Users should have a clear, unobstructed view of the container inlet opening
- The container should be located within arm's reach
- The fixture height should be below the eye level of 95% of adult female workers

4.7 *Materials:* All materials are excluded which emit ozone depleting substances (ODS) or toxic emissions during combustion,

4.8 *Reliability:* 100% of Safety boxes and incinerator containers are to remain physically intact and satisfactory for use when used in compliance with the performance specifications defined above.

4.9 *Maintainability:* Product is a consumable item with no maintenance requirement.

4.10 *Disposal and recycling:* Safety boxes or incinerator containers are disposed after a single use cycle in WHO pre-qualified disposal devises.

4.11 *Instructions:*

Pictorial instructions in English, French, Spanish and Arabic to be printed on two sides of the container to clearly describe:

- use of the box as a container for contaminated syringes;
- disposal of the box;
- Incineration of the box.

A separate sheet to be provided with pictorial instructions on how to assemble the flat-packed packages; at least one sheet per twenty boxes.

4.12 *Training:*

- Training instruction applicable to waste handlers is provided for assembly of the box or container in the form of a step by step procedure written directly on the safety box or the incinerator container.
- Training instruction applicable to health workers is provided in a guideline to
be used during routine staff training.

5. **Packaging:** No special requirements

6. **On-site installation** Not applicable

7. **Product dossier:**
   - Manufacturer technical and performance specifications
   - Experience of the manufacturer/supplier and references
   - A statement of compliance with pre-defined Norms
   - Terms of warranty, service and other after sales maintenance arrangements proposed
   - Management requirements for supervisors and managers
   - Training in Audit/Inspection Requirements with regard to safety and operation
   - Adequate manuals addressing safety, operation and waste handling, and training.

8. **On-site maintenance:** None required

9. **Change notification:** <state how the manufacturer or approved installer is to report future changes in product specification, manufacturing location and manufacturing methods to WHO/UNICEF and define the conditions under which re-testing may be required> **WHO to Define**

10. **Defect reporting:** <state how the manufacturer or approved installer is to notify purchasers, end-users and WHO/UNICEF in the event of safety-related product recalls, component defects and other similar events> **WHO to Define**

**Annexes:** None

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**Revision history:**

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# SECTION C

## MARKET SURVEY

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TITLE: Verification Protocol for Safety Box and Incineration Container

Product verification protocol:  <PQS category>/<unique reference>
Applies to specification ref(s):  <PQS category>/<unique reference>
Date of origin:  <Date>
Date of last revision:  <Date>

1. Scope:
The type examination protocol for safety boxes and incinerator containers sets out the guidelines for systematic inspection and evaluation of the product for adhering to the performance specifications developed. It also evaluates the compliance of the product to certain minimum international standards.

2. Normative references:
   b. Selecting, Evaluating and Using Sharps Disposal Containers, DHHS (NIOSH) Publication No. 97-111

3. Terms and definitions: <define any specific terms used in the protocol, particularly terms which may not be widely understood>

4. Applicability: <state who will carry out the sample examination and state who will carry out on-site inspection of the manufacturer’s production facilities (where relevant)>

5. Sample-examination checklist
   5.1 Type examination certificates: < list acceptable type-examination certifiers and state the form in which evidence of type-examination is to be provided >
   5.2 Number of samples: <state minimum number of samples to be evaluated>
   5.3 Sample checklist: <list product features that are to be examined and describe how each item in the list is to be evaluated, including ergonomic, health and safety and ‘Universal Design’ features>

Initial inspection
   • Brand Details
     Record by visual inspection
• Instructions
Record the presence or absence of instructions and include a copy in the report.

• Dimensions and Weight
Record the external dimensions and the weight of the box empty.

Further inspection

• Ease of filling
A panel of 2 people should be used to assess the ease of filling. 100 uncapped auto-destruct syringes, 0.5 ml with needles should be loaded into the box and/or by each assessor. If syringes stack, the container may be gently shaken. After filling the container with 100 syringes, additional syringes are inserted to determine the maximum capacity. The container is considered full when the filling line is reached or inserting of the syringe requires shaking or special attention.

The assessors should note any difficulties or inaccuracies in the instructions. After loading the boxes they should be inspected for signs of damage (eg, needles piercing sides).

• Test criteria for qualification:
  ➢ The container must be able to contain 100 uncapped auto-destruct syringes, 0.5 ml with needles.
  ➢ No needle should pierce any of the sides, even when fully loaded till the filling line.

Ignition and combustion tests

A sample of syringe incinerator box should be filled with EPI disposable or auto disable syringes with fixed needles, so that no further syringes can be placed inside without them protruding or falling out of the loading opening. The combustion test should then be performed with the box on a test bed with the top of the box facing into a light to gentle breeze (2-5 m / sec) - the breeze may be generated by using a motor driven fan.

The syringes should be ignited using the fire/lighters supplied by the manufacturer and the combustion process monitored (use either a video camcorder or still photography).

The ease of ignition, the combustion time and completeness of combustion should be noted. In addition the ability of the box to contain the fire, including any leakage of molten materials, should be noted.

If ignition is unsuccessful, then the test should be repeated with the box filled to a level corresponding to the lower edge of the loading flap.

• Test criteria for qualification:
Container shall allow for syringes to completely burn without spillage of contents.

Durability

- Needle Penetration Test
  Follow the method of the test describe in BS 7320: 1990 except that the hypodermic needles used should be those fitted to prototype auto-destruct syringes.
  
The force measured for each penetration should be recorded.
  
  ➢ Test criteria for qualification
  The average of forces needed to penetrate samples taken from each position shall be not less than 15 N, and the force required to penetrate any one sample from wherever taken shall not be less than 12.5 N.

- Resistance to water
  Store one sample of box fully loaded in a pool of water 5 mm deep for 48 hours.
  At the end of this period the box should be inspected for deterioration.
  
  If the box is intact after the above test an ignition and combustion test should be carried out and comments made on the burn.
  
  ➢ Test criteria for qualification
  a. The wet container should withstand intense shaking for 20 times without spillage of content or needles piercing through the sides
  b. The wet container shall allow for syringes to completely burn without spillage of contents.

- Tumble Test
  A sample box should be filled with auto-destruct syringes to the lower edge of the loading flap. The incinerator should then be placed in a large tumble box and subjected to 100 drops of 800 mm each. The box should be inspected for piercing or any signs of deterioration after the following number of drops: 5, 10, 50, 100.
  The test should be stopped if the inspection reveals more than one needle has penetrated.

  ➢ Test criteria for qualification
  a. No syringe should fall out of the container.
  b. Not more than 1 needle shall pierce through any of the sides.
  c. The box shall not be seriously deteriorated in any way.

5.4 Criteria for qualification: <state the minimum requirements for pre-qualification>

6. Quality control checklist
6.1 **Quality control standards:** <list acceptable quality control standards (e.g. ISO 9001) and state the form in which evidence of conformity is to be provided>  

In the absence of international standards for safety boxes, the WHO specifications E10/IC.1 for safety boxes and incineration containers and E10/IC.2 for safety boxes can be used to determine procurement requirements.

6.2 **Quality control checklist:** <list the production quality control features that are to be examined in the course of the on-site inspection (if applicable)>

6.3 **Criteria for qualification:** <state the minimum requirements for pre-qualification> (repeated)

7. **Pre-qualification evaluation:** <state the overall minimum requirements for pre-qualification taking account of results from 5.4 and 6.3 and including any weighting system that may be needed>

8. **Modified products:** <describe the procedure for re-checking products that are already pre-qualified, but which have subsequently been modified by the manufacturer. This procedure may not involve full re-verification.>

**Annexes:** <as required>

**Revision history:**

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