PQS performance specification

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1. Scope

This specification describes the performance requirements for sharps safety boxes, constructed of cardboard or other materials, intended safely and efficiently to contain, store, transport and dispose of used sharps.

2. Normative references:

AS 4031:1992: *Non-reusable containers for the collection of sharp medical items in health care areas.*
BS 7320:1990: *Specification for sharps containers.*
DHHS (NIOSH) Publication No. 97-11: *Selecting, Evaluating and Using Sharps Disposal Containers.*

3. Terms and definitions:

Auto-disable or AD syringe: A syringe and needle assembly, of any capacity, complying with ISO 7886 – part 3: 2005, or later edition.
Reuse prevention feature syringe: A syringe and needle assembly, of any capacity, complying with ISO 7886-4: 2006, or later edition.
Disposable syringe: A syringe and needle assembly, of any capacity, complying with ISO standard 7886 – part 1: 1993 or later edition.
In writing: means communication by letter, fax or email.
Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Maximum capacity: The number of 0.5ml AD syringes that a sharps box can contain without syringes projecting above the fill line printed on the outside of the container.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.

Syringe: An auto-disable, syringe with reuse prevention feature or disposable syringe and needle assembly.
Sharps safety box: A container intended to safely hold used sharps.
Sharps: In this context: syringes and needles; sharps syringes and needles, phlebotomy devices, IV insertion needles, including butterflies, lancets, scalpels and suture needles, 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 with it.

4. Requirements:

Poorly managed sharps waste exposes health workers and the general community to injuries, infection and environmental pollution. The efficient, safe and environmentally acceptable management and disposal of such waste ensures that sharps are contained and that the risks of needle-stick injury, air and ground water pollution are minimized.

4.1 *General:*

Sharps safety box of 1.25[1], 2.5, 5, 10, 15 or 20 litre nominal storage capacity intended safely and efficiently to contain, transport and store used sharps until final destruction, safe disposal or recycling.

4.2 *Performance:*

4.2.1 Functionality:

The safety box must safely contain contaminated sharps:

- at the point of use;
- during temporary storage;
- during handling and transport to the point of treatment and final disposal.

4.2.2 Shipping and storage volume before use:

Boxes must be supplied flat-packed or nested to minimize shipping and storage volume.

4.2.3 Nominal capacity:

Boxes must accept no less than 20 nbr. 0.5ml AD syringes per nominal litre of storage capacity. This capacity is to be achieved when syringes are dropped in randomly, needle first, with 25mm unsheathed non-retractable needles attached and plungers fully depressed. No syringe must protrude from the container or above the fill line and the box must be capable of being correctly and permanently closed without any risk of needle-stick injury.

4.2.4 Maximum capacity:

The maximum capacity is allowed to exceed the nominal capacity of 20 syringes per nominal litre provided all the conditions of clause 4.2.3 still apply.

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[1] The 1.25 litre sharps safety box is intended primarily or use in settings where community health workers give small numbers of routine injections outside health facilities. Typically the boxes will be used to dispose of standard AD immunization syringes or compact pre-filled injection devices.

4.2.5 *Sharps aperture:*
Boxes must be fitted with a sharps aperture, capable of receiving syringes and needle assemblies of all standard sizes up to and including 20 ml, together with other sharps. It must be possible to close and seal the aperture at any time between empty and full to maximum capacity. The closure mechanism must pass the test for security of attachment of aperture closure devices described in BS 7320:1990, Appendix B.

4.2.6 *Handles:*
Boxes must be supplied with a handle or other lifting device which allows the container to be carried safely with one hand. The lifting device must be positioned above the fill line, must not obstruct access to the sharps aperture, and must be sufficiently robust to ensure that it does not to break during use and during transport to the disposal site. It must remain attached to the box when the box is filled with sharps to its maximum capacity and tested in accordance with BS 7320:1990, Appendix A.

4.2.7 *Colour:*
Boxes can be the colour of unbleached sulphate board, or non-chlorine bleached white, or yellow.

4.2.8 *Bio-hazard marking:*
Boxes must be clearly marked with the international bio-hazard warning not less than 50mm diameter, printed in black or red on each of the front and back faces of the box. Refer to Annex 1.

4.2.9 *Fill line:*
The maximum recommended fill line must be clearly marked on all vertical faces of the box, in black or red.

4.2.10 *Resistance to penetration:*
The average of forces needed to penetrate samples taken from each position must not be less than 15 N, and the minimum force required to penetrate any sample taken from any position must not be less than 12.5 N.

4.2.11 *Resistance to damage during drops from height:*
Boxes must pass the drop test described in **E10/SB01-VP**. After 100 drops, no syringe should have fallen out of the container; the box should not be seriously damaged, and no more than one needle should have penetrated the container walls.

4.2.12 *Stability and spillage:*
Boxes must not tip over when placed on a 15 degree non-slip plane with its short axis parallel to the line of tilt in general accordance with the test method in AS 4031:1992, Appendix D. If overturning occurs, the arrangement of the sharps aperture should minimize the risk that sharps are spilled.

4.3 *Environmental requirements:*

4.3.1 *Temperature resistance:*
Cardboard boxes, filled to their maximum capacity, must be able to resist temperatures of up to 170°C for periods up to 30 minutes without spilling any part of the load.

4.3.2 *Water resistance:*
Boxes, filled to their maximum capacity, must be able to withstand 48 hours at 43°C and 90% relative humidity in 5 mm of water, without spilling any part of the load.

4.4 *Physical characteristics:*

4.4.1 *Overall dimensions:*
Assembled box dimensions should be selected to accommodate the full range of sharps, as defined in clause 3, and to allow effective filling of the box.

4.4.2 *Minimum dimensions:*
The minimum height from the bottom of the container to the fill line must be no less than 150mm for 2.5 litre boxes and 230mm for other sizes.

4.4.3 *Sharps aperture dimensions:*
38 mm diameter, or 38mm width and breadth. Larger apertures are allowed, but must be fitted with an engineered protective feature – for example a flange on a plastic safety box.

4.4.4 *Weight:*
No specific restriction, consistent with keeping shipping weight to a minimum.

4.5 *Interface requirements:*
External dimensions should be chosen to allow the box to fit within the treatment loading mechanisms.

4.6 *Human factors:*

4.6.1 *Sharps aperture marking:*
The aperture must be clearly visible against the colour of the container.

4.6.2 *Tamper-proofing:*
To reduce the risk of needlestick injury, the lowest point of the sharps aperture must be at least 50 mm above the maximum recommended fill line marked on the exterior of the box.

4.6.3 *Handling:*
It must be possible to carry the box in one hand without spillage of contents and without risk of needle stick injury, both before and after final closure of the sharps aperture.

4.7 *Materials:*
The following materials are permitted:

- Bio-degradable cardboard-based materials – post-consumer recycled material is preferred;
- Other bio-degradable board materials.
- Non-toxic inks, glues and dyes.
- Hard recyclable plastic (plastic containers should not be incinerated).
- Metal.

If incineration is the final treatment option, the following materials are not permitted:

- Materials which are not bio-degradable.

- Materials which emit ozone depleting substances as defined in the Montreal Protocol;
- Materials which generate toxic emissions during incineration at any temperature between 650°C and 1,200°C;
- Materials which release gases with a high global warming potential.

4.8 *Warranty:*
100% of boxes are to remain physically intact and satisfactory for use when used in compliance with this performance specification.

4.9 *Servicing provision:*
The product is a consumable item with no maintenance requirement.

4.10 *Disposal and recycling:*
Boxes are disposed of after a single use cycle if made of cardboard. If made of plastic or metal, they are typically taken to a treatment site to be reused, recycled or disposed of.

4.11 *Instructions:*
In addition to the international bio-hazard symbol, clear pictorial instructions without writing are to be printed on two sides of the container showing:
- How to assemble the box.
- How to use the box as a container for contaminated sharps;
- Syringe disposal direction (needle down).
- How to close the sharps aperture when the box is full.

4.12 *Training:*
Training on the assembly, use and disposal of safety boxes will be provided by the health care programme when the boxes are first introduced, and subsequently during supervisory visits

4.13 *Verification:*
In accordance with PQS Verification Protocol **E10/SB01-VP**

5. Packaging:
Recyclable cardboard is to be used.

6. On-site installation :
Not applicable.

7. Product dossier :
The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:
- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.

- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer's ISO 9001 2000 quality system certification.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- One sample of each size and type of box. One sample of the instruction insert.
- Indicative cost of the product per 100, 1,000 and 10,000 units, EXW (Incoterms 2000).

8. On-site maintenance:
None required.

9. Change notification:
The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting:
The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

11. Annex 1 – International bio-hazard symbol[2]

Colour red or black

50mm minimum
diameter

[2] Source: Laboratory biosafety manual (Third edition) World Health Organization, Geneva 2004.

Revision history:			
Date	Change summary	Reason for change	Approved
01.06.2007	Changes in response to WHO internal review.		UK
05.07.2007	Further changes in response to WHO internal review.		UK
13.08.2007	2. AS 4031 added. 4.1: 1.25 litre option added. Footnote added. 4.2.11: wording changed.	Request from the field. Clarification.	UK
13.09.2007	4.2.7: material clarified. 4.2.8: 'four' omitted. 4.4.2.: dimension changed. 4.7: 'glue' added. 4.11: 'in writing' added.	Manufacturers review comments	UK
28.09.2007	4.2.1: 'Sharps' deleted from first bullet point.. 4.2.7: Title changed. 'or yellow' added. Biohazard marking reference removed. 4.2.8: New biohazard marking clause added. Subsequent clauses re-numbered. 5.3.1: 'Card' omitted. 'Cardboard' added.	Incorporation of PATH comments to extent agreed during internal review	UK