Annexure 1

Tamil Nadu Health Systems Project

Infection Control and BioMedical Waste Management

TITLE: Needle cutter for Health Waste Management

Specifications Reference: WHO guidelines

a. Specification reference: E10/NC01.1 of WHO

b. Product verification protocol: E 1 0/NC01-VP.1

c. Date of origin: 03.07.2008

d. Date of last revision: New specification; 04 March 2009

Contents:

1. Scope:

This specification describes the performance requirements for manually operated needle cutting devices which safely disable used needles and syringes.

2. Normative references:

A. AS 4031-1992	: Non-reusable containers for the collection of sharp medical items used in health care areas.
B.BS 7320:1990	: Specification for sharps containers.
C.ISO 9001: 2000	: Quality Management Systems – Requirements.
D.ISO 14001: 2004	: Environmental management systems - Requirements with guidance for use.
E.ISO/IEC 17025: 2000	: General requirements for the competence of testing and calibration laboratories.
F.ISO 20282-1: 2006	: Ease of operation of everyday products - Part 1: Context of use and user characteristics.
G.IEC 60068-2-32: 1975	: Environmental testing – Part 2: Tests. Test Ed: Free fall
H.ISO 7864:1993	: Sterile hypodermic needles for single use
I.ISO 7886-1:1993	: Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use
J.ISO 7886-3:2005	: Sterile hypodermic syringes for single use -- Part 3: Auto disable syringes for fixed-dose immunization
K.ISO 8537:2007	: Sterile single-use syringes, with or without needle, for insulin

3. Terms and definitions:

A. Cutting assembly: That part of the device which contains the cutting or shearing mechanism, which, when connected to a needle container constitutes the complete needle cutter device. The cutting mechanism and container can be integral or separable.

B. In writing: means communication by letter, fax or email.

C. Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labeling 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.

D. Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

E. Needle: In this context, includes the needle hub.

F. Needle cutter: A device which renders a plastic syringe of any type safe by removing, cutting or destroying the needle, needle hub, or syringe nozzle and which encloses the remains of the needle in a needle container.

G. Needle container: That part of the device which stores cut, sheared or otherwise disabled needle remains prior to final disposal. The needle container can be an integral, non-detachable part of the device or can be removable. Separable needle containers can be designed to be either disposed of when full, or emptied, cleaned, and reused.

H. 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.

4. Requirements:

4.1 General:

A manually operated needle cutter comprises a cutting device and a needle container which allows health workers to make used syringes safe and harmless at the point of use immediately after administering an injection. Where not intended for stationary applications, the device should be easily portable. The device must be safe, easy and convenient to use, easily cleaned, affordable and reliable.

Needles or needle residues are stored until the needle container is filled up to its designed maximum fill line, at which point the container must be removed, capped, and either disposed of or emptied. In the case of disposable needle cutter devices with integral containers and cutting assemblies, it should be ensured that the entire device is disposed of properly.

4.2 Performance:

4.2.1 Needle size:

The device should disable wet or dry needles, 10-76 mm in length and 18-28 gauge in diameter.

4.2.2 Needle/syringe type:

The device should disable all ISO compliant syringe/needle combinations.

4.2.3 Needle insertion:

All needles in the size range specified in clause 4.2.1 should insert easily into the device, with little or no force.

4.2.4 Cycle time:

Needle removal or cutting devices should have a maximum cycle time per needle not exceeding 5 seconds.

4.2.5 Needle entry geometry:

The needle aperture must be designed so that the needle can be inserted into the port at any angle lying within a 60 degree cone whose apex is centred on the aperture.

4.2.6 Complete cutting:

The cutting blade configuration should ensure that the needle, needle hub, or syringe nozzle is completely cut or sheared. Incomplete shearing or other modes of disabling the needle, such as crimping or bending, are not allowed.

4.2.7 Self-clearing mechanism:

The cutting mechanism must be self-clearing. Syringe or needle remnants remaining in the device must not impair its operation.

4.2.8 Needle container attachment:

The needle container, if separable, must attach securely to the device so that tipping or dropping it does not separate the container from the cutting assembly.

Attachment of the needle container to, and subsequent removal from the cutting assembly should be safe, clean and easy. There must be no risk of needle stick injury during these operations.

4.2.9 Operating life:

• Non-disposable devices: must withstand at least 100,000 cycles of operation, and require no major maintenance or user intervention, other than cleaning and lubrication, no more frequently than once every 10,000 cycles of operation.

4.2.10 Splatter:

During or after normal use of the device, there should be no detectable contamination of:

• Exposed skin, mucous membrane, or clothing of the operator.

• Work surfaces or other surfaces adjacent to and surrounding the device.

• The outer surfaces of the device which are accessible to the user, with the exception of the needle entry target area.

4.2.11 Drop test (complete device):

The performance and safety of the cutting assembly must not be compromised by dropping from a height of 1,000mm onto a smooth concrete surface in accordance with the test method in IEC 60068-2-32. In devices with a removable needle container, the container must NOT be detached.

4.2.12 Drop test (needle container only):

The container when full of needles and with the closure device engaged should be dropped 100 times onto a smooth concrete surface from a height of 1000mm.

No needles must fall out of the container. Not more than one needle must pierce any of the sides. The container must not be seriously damaged by the test.

4.2.13 Tilt angle:

The device must not tip over, whether empty or full, 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.

4.2.14 Leak-proof:

The device must not leak any liquid contents when placed in the upright position at any angle between 0 and 15 degrees.

4.2.15 Needle escape prevention:

The cutting assembly must be designed to prevent the migration of cut needles from the needle container into the needle aperture.

4.2.16 Cutting device closure mechanism;

If the device is intended to be carried with the needle container attached, the needle aperture must have a closure mechanism to prevent needles from falling out of the attached needle container in any orientation of the assembly.

4.2.17 Needle container closure mechanism

If the needle container is intended to be detachable, it must have a secure closure mechanism that prevents spillage of sharps after detachment from the cutting assembly, whatever the orientation of the container. Preferably the closure mechanism should engage automatically upon removal of the full

container from the cutting assembly. The container must pass the dropping, toppling and leakage tests described in BS7320:1990, Appendix D and Appendix E.

4.2.18 Needle container puncture resistance:

The needle container must pass the penetration resistance test in BS7320:1990, Appendix C.

4.2.19 Needle container capacity:

The needle container must hold at least 150 nbr. 20mm needles, and/or needle remains, without affecting operation of the device.

4.2.20 Needle container capacity indication:

The needle container must be translucent enough to allow the user visually to detect the level of needles in the container. The sides of the container must be clearly marked with a fill line in accordance with BS7320:1990.

4.2.21 Tamper proofing:

The needle aperture must be designed to prevent any part of the hand from entering. Needles should not protrude from the needle container when it is filled up the level of the fill line.

4.3 Environmental requirements:

4.3.1 Operating environment:

The performance of the device must not be compromised by exposure to continuous ambient conditions of 43°C and 90% relative humidity for a period of one week when the needle container is in any condition between empty and full.

4.3.2 Chemical resistance:

The device should be resistant to saline solution and to mild chemical cleaning agents, including diluted bleach.

4.3.3 Bio-hazard marking:

The needle container must be clearly marked with the international bio-hazard warning not less than 35mm diameter, **printed in black or red**, on each of the front and back faces of the box.

Refer to Annex 1.

4.4 Physical characteristics:

4.4.1 Overall dimensions:

If intended to be portable, the device must be compact and have minimal protrusions. It must be transportable over long distances on foot by the lowest quartile of female operator without inconvenience and with minimal dismantling.

4.4.2 Weight:

If intended to be portable, the empty device, complete with empty needle container, should weigh a maximum of 750 grams.

4.5 Interface requirements:

4.5.1 Disposal:

The needle container or integral cutter and container, if disposable, must be able to fit into a protected needle pit with a 10 cm inner diameter entry tube.

4.6 Human factors:

4.6.1 Generally:

The product must be useable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including long-sighted and short-sighted people without glasses, in accordance with the general principles laid out in ISO 20282-1: 2006.

4.6.2 Skill level:

It must be possible for health workers to operate the device with minimal training.

4.6.3 User position:

The device must be comfortable to operate by 5th to 95th percentile adults in standing and seated positions with the device resting on a firm surface.

4.6.4 Handedness:

The device must be equally useable by left and right handed health workers.

4.6.5 Activation force:

The maximum force required to cut a standard (21 g) needle, needle hub, or syringe nozzle should not exceed 67 N.

4.6.6 Repetitive use:

The alignment of the cutting mechanism handles should avoid ulnar deviation and should be designed to prevent discomfort or the occurrence of repetitive strain injuries when the device is routinely used by a single operator for 200 cycles per day.

4.6.7 Pinch points:

Normal use should not result in pinching of the operator's hands.

4.6.8 Smoothness of operation:

Complete needle removal or destruction must be achieved with a single smooth hand movement.

4.6.9 Hand to needle distance:

The distance from the needle to the hand holding or operating the needle cutter must exceed 50 mm while operating the device.

4.6.10 Blade edge protection:

The device's cutting blades must not expose the user to cut hazards, either with or without the needle container connected.

4.6.11 Cleaning:

External parts and reusable internal parts accessible to the user must be cleanable with standard mild cleaning agents.

4.7 Materials:

4.7.1 Generally:

The materials used must be selected to minimize surface degradation or corrosion arising from repeated use up to the specified minimum number of operating cycles, when the device is cleaned and lubricated in accordance with the manufacturer's recommendations.

4.8 Warranty:

The device must be warranted to meet all physical and performance requirements defined in this specification over the relevant operating life as specified in clause **4.2.9.**

4.9 Servicing provision:

• Non-disposable devices: The only maintenance required during the design life of the device should be consumable part replacement, regular cleaning and lubrication. The minimum life cycle of consumable parts should be 25,000 removals, cuts or destruction cycles. Three additional sets of consumable parts should be provided with the device, together with product-specific service tools, if required. Used consumable parts should not be re-furbished but must be disposed of in the needle container.

4.10 Disposal and recycling:

Device must be able to be disposed of in the medical waste stream in accordance with the prevailing Bio-medical Waste Management Rules prevailing in India.

4.11 Instructions:

User and maintenance instructions must be available in English and Tamil. Labeling on the device should include clear pictorial instructions.

4.12 Training:

Training on the assembly, use and maintenance (if any) of the device will be provided by the health care programme when the device is first introduced, and subsequently during supervisory visits.

4.13 Verification:

In accordance with PQS Verification Protocol E10/NC01-VP.1 of WHO.

5. Packaging:

Materials used for packaging the finished product are to be free of ozone depleting compounds as defined in the Montreal Protocol. The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. On-site installation:

Not applicable

7. Product dossier (complete set of documents) :

The legal manufacturer or reseller is to provide TNHSP with a pre-qualification dossier containing the following:

• 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. (If applicable)

• 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.

• 2 complete samples of the device, including spare parts and instructions.

• Indicative cost of the product per unit, *per 100 units and per 1,000 units EXW

(Incoterms 2000).

8. On-site maintenance:

If required, will be carried out by the user.

9. Change notification:

The legal manufacturer or reseller is to advise TNHSP 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 TNHSP in writing in the event of safety-related product recalls, component defects and other similar events.

Annex 1 – International bio-hazard symbol