TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR POSTMORTUM DEPARTMENT

Ministry of Health and Family Welfare
Government of India

INDEX

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INTRODUCTION

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufactures' industry associations/government organizations.

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with experts has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise.

In the consultative meeting experts has mentioned the following activities needs to be considered wisely while procuring medical devices.

(1) The public health facility that intend to house medical devices (especially electrical/electronic based) must ensure before installation ,
(a) Proper grounding at electrical sockets,
(b) Wherever generator or UPS or solar power is used as back up energy source, should ensure the stabilizer/surge protector to prevent malfunction of medical devices. The same may be undertaken at facilities having voltage/energy fluctuations.
(2) Procurer may form rate contract on reagents/consumables anticipating yearly demand, on Medical devices which require periodic supply of reagents/consumables for its day to day operation.
(3) Appropriate filtering mechanism to be housed at public facility to ensure maximum longevity on Medical devices which operates efficiently depending on quality of pneumatics/water supply source.
(4) Ensure compliance for Medical devices which are regulated under various laws/regulatory body like CDSCO, AERB, Pollution control Board, PC PNDT, PESO etc.
(5) Procurer/public health facility must ensure scheduling calibration and preventive maintenance (incl. replacement of parts that are expected to be worn out after certain operation) as recommended in Medical device manufactures operational/service manual.
(6) Wherever necessary warning/safety information required, has to be placed at public health facilities.
(7) User/ In-house service training to be procured along with Medical devices for effective utilization.
(8) Public health facility may actively engage with MoHFW initiative, Post market surveillance /Materiovigilance program of India.
(9) Public health facility have to rely on manpower availability or utilization or IPD/OPD load factor to decide on quantity of medical devices to be procured and not just on number of bed at each level.

Autopsy (Mortuary) Table

Version no. :	Draft_1
Date:	03/09/2018
Done by : (name.institution)	HCT/NHSRC
NAME, CATEGORY AND CODING	
UMDNS name	Autopsy Tables
UMDNS code(s)	5246
GENERAL	
1. USE	
1.1 **Clinical purpose**	This tables are used ~~mostly~~ for post-mortem examination ~~pathologic investigations~~ and for demonstration purposes.
1.2 **Used by clinical department/ward**	Postmortem Department
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1 ~~**List of instruments**~~ **Technical Characteristics**	1. Elevating with stainless steel dissection board (straight table, not L type), Dimension:100”L x 40”W. Integrated sink should also have same length and width. 2. Elevating height 32” to 40’ up and down pedestal control. All thick gauge heavy duty anticorrosion stainless (SS 304) construction ~~with Elevating/rotating down draft table~~. 3. Table top and integrated sink fabricate of minimum 14 gauge stainless steel, anticorrosion pedestal of minimum 11” gauge stainless steel with satin finish. Minimum 1/2” removable perforated grid plate with 3/8” diameter hole on 2” centres (4 each). 4. Large double wall Sink with regular removable sprinkle system, Handy spray, rinse facility. Faucets stainless steel. Hand shower: heavy duty chrome plated hand piece durable minimum 8’ long flexible hose Hand piece with hose drop in deck. Concealed pressure control hot and cold water mixture/swing spout/tap. ~~Hot/cold mixing valve~~. ~~down draft canes~~ Hydro aspirator with reverse flow having built in vacuum breaker. Access panel 2 outlet curved moulded sides of table (Stainless Steel). ~~4. Dissection Station ‘L’ shaped extension. Same gauge stainless steel extension with drainage facility and water supply (Hot and Cold)~~ 5. (L) 70”X30” (W) for dissection of internal organs. Extension should have independent fixed pedestal and not attached to autopsy table as pedestal is fixed. The edger should be curved, moulded and raised. Electrical outlets should be water splash proof. 6. Table should be able to mount in position that allow surgeon to move around the table. 7. Table should have engraved scale for cadaver measurement in centimetres and inches. 8. Rivets or bolts on table should not enable bacterial or microorganism growth or accumulation.
2.2 **User's interface**	Table should be height adjustable.

2.3	**Software and/ or standard of communication(where ever required**	Not required
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	As mentioned in technical characteristics, if the room size permits.
3.2	**Weight (lbs, kg)**	200Kg or less.
3.3	**Noise (in dBA)**	Less than 50dbA.
3.4	**Heat dissipation**	Not applicable
3.5	**Mobility, portability**	Fixed.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	230V AC/1 phase/ 50Hz.
4.2	**Battery operated**	Not required
4.3	**Protection**	NA
4.4	**Power consumption**	Less than 100W.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Organ cutting table, sprinkle system with wrist control water tap, neck rest, body support sheet and head rest.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of working in 50-100% humid condition and in temperature range of 5-40 degree Celsius.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Should be compatible with Medical grade disinfectant solutions like Cidex or hydrogen peroxide solution.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. ~~Should be FDA/Europen CE/BIS approved product.~~ The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer ~~and Supplier~~ should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Comply with IS 7036 autopsy table. ~~4. Shall meet IEC 60601-2-38 General Requirements of Safety for Medical Electrical Equipments part 2-38 Particular requirements for safety of Electrically Operated Hospital Beds Electromagnetic Compatibility.~~ ~~5. The manufacturer must have a management system certified to ISO 9001.~~ 5. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		

8.1	**Pre- installation requirements: nature, values, quality, tolerance**	The supplier should install (including plumbing and electrical).
8.2	**Requirements for sign-off**	Compliance with quantity checklist, Quality check of the product.
8.3	**Training of staff (medical, paramedical, technicians)**	Hands on training to be provided to healthcare professional on using table, day to day maintenance/cleaning. Hand on training for in-house (Biomedical engineers) preventive/corrective maintenance (hardware/software).
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares parts and accessories. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	One copy (hardcopy and softcopy) to be provided on user manual/operating manual and service/Technical manual.
10.2	**Other accompanying documents**	1.Certification on quality of stainless steel. Compliance with autopsy table standards or regulation. 2.Document illustrating frequency of calibration or preventive maintenance by manufacturer.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc) rate available to be declared by the manufacturer.Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms. 3. Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed on autopsy table.

Post-Mortem Equipment Set

Version no. :	Draft_1
Date:	03/09/2018
Done by : (name.institution)	HCT/NHSRC

NAME, CATEGORY AND CODING

UMDNS name	Amputation Saw, Bowel surgical Scissors, Post Mortem Scissors, Chisel, Detachable Cross handle chisel, Brain Knife, Cartilage Knife
UMDNS code(s)	13922,14250,14181,14055,21023,19816, 19818

GENERAL

1. USE

1.1	**Clinical purpose**	Post mortem instruments for autopsy surgeon ~~pathologists~~ providing the examination of corpses during autopsy. Below list of instruments are for single autopsy table.
1.2	**Used by clinical department/ward**	Post Mortem Department

TECHNICAL

2. TECHNICAL CHARACTERISTICS

2.1	**List of instruments**	1. Amputation Saw 12” -1 Quantity 2. Bowel Scissors 7" ~~1~~ 4 Quantity 3. Post Mortem Scissors 6" ~~1~~ 4 Quantity 4. Blow Pipe straight 8" 2 Quantity 5. Hammer with chisel 8” 1 Quantity 6. Detachable Cross handle chisel 3.5” 1 Quantity 7. Skull Rest 7” 1 Quantity 8. Brain Knife 9.5” 1 Quantity 9. Caltin Knife 9.5” 1 Quantity 10. Cartilage Knife 7.5” 1 Quantity 11. Scalpel 16” 4 Quantity 12. Dissecting Forceps 6” 1 Quantity 13. Chain hook set of 3, 3” 1 Quantity 14.Scalpel Handle 127 mm 1 Quantity 15. Organ knife and saw 22mm blade 1 Quantity 16 Bistoury Knife 70mm blade 1 Quantity 17 Rib Knife 1 Quantity 18 Pelvic Organ Knife 1 Quantity 19 Dissection scissors 1 Quantity 20 Bone cutting scissors 1 Quantity 21 Needle Holder 1 Quantity 22 Raspatory 1 Quantity 23 Retractor 2 Quantity 24 Osteotome 2 Quantity 25 Vagotome 1 Quantity 26 Surgical needles 12 Quantity 27Folding rulers 300 mm 2 Quantity 28 Probes with eye/fish tail 2 Quantity 29 Measuring/specimen jar (100 ml and 1 Litre) 1 Quantity 30 Rib Shears

		31 Magnifying lens 1 Quantity 14. Box Containing all these instruments 1 PC
2.2	**User's interface**	~~NA~~ All knifes should have stainless steel handle and surgical quality.
2.3	**Software and/ or standard of communication(where ever required**	~~NA~~ Not required
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	~~NA~~ As specified in IS/ISO standards.
3.2	**Weight (lbs, kg)**	~~NA~~ As specified in IS/ISO standards.
3.3	**Noise (in dBA)**	Zero
3.4	**Heat dissipation**	Zero
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	Zero
4.2	**Battery operated**	Zero
4.3	**Protection**	Not required.
4.4	**Power consumption**	Zero
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Protective SS 304 case for clean storage and safe transport.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		

6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of working in 50-100% humid condition and in temperature range of 5-40 degree Celsius.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Should be compatible with Medical grade disinfectant solutions like Cidex or hydrogen peroxide solution.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1.The surgical instruments should be made using top quality medical grade hardened stainless steel with defined specifications like IS 5589, IS 10414, IS6989, IS6990, IS6996, IS 3318 IS3320, IS 6442 etc. 2. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Not required
8.2	**Requirements for sign-off**	Compliance with quantity checklist, Quality check of the product.
8.3	**Training of staff (medical, paramedical, technicians)**	Hands on training to be provided to healthcare professional on using post mortem equipment set , day to day maintenance/cleaning.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	One copy (hardcopy and softcopy) to be provided on user manual/operating manual and service/Technical manual
10.2	**Other accompanying documents**	Certification Documents implying compliance to standards.
11. Notes		

11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc) rate available to be declared by the manufacturer. 3.Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms. 4. Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed on each instrument.

Autopsy Weighing Machine – Organ

Version no. :	Draft_1
Date:	03/09/2018
Done by : (name.institution)	HCT/NHSRC

NAME, CATEGORY AND CODING		
UMDNS name		Autopsy scale
UMDNS code(s)		5612
GENERAL		
1. USE		
1.1	**Clinical purpose**	Stainless steel scales capable to measure the weight of an organ.
1.2	**Used by clinical department/ward**	Postmortem Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Capacity: 0 - 20 Kg with Accuracy of 1 gram. 2. Building: Stainless Steel housing. 3. Display: 6 digits LCD . 4. Function like Gross Weight - Net Weight - Tare - Auto-zero should be available. 5. Stainless steel weighing pan, approximately 80 mm diameter. ~~7. Full glass windscreen, able to be opened on both sides and from the top cover.~~ ~~8. Adjustable feet (so the balance can be levelled).~~ 6. Waterproof display and keypad, sealed by a durable flexible membrane. 7. Background illuminated (backlit) display with digits at least 15 mm high. 8. Level indicator in the view field of the display. 9. Built-in motorized calibration of weight with automatic adjustment (or calibration using an external standard weight). 10. Readability: 0.0001 g (0.1 mg). 11. Repeatability: 0.0001 g (0.1 mg). 12. Linearity: 0.0002 g (0.2 mg).
2.2	**User's interface**	Manual, English Menu
2.3	**Software and/ or standard of communication(where ever required**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	In approximate range of 600 (L)X 300 (W) X 300 mm (H) or lesser
3.2	**Weight (lbs, kg)**	Less than 5Kg.
3.3	**Noise (in dBA)**	Noise pressure level: ≤60 dbA.
3.4	**Heat dissipation**	Almost Zero.
3.5	**Mobility, portability**	Portable

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	230V AC/50Hz/1Phase
4.2	**Battery operated**	Yes
4.3	**Protection**	Stabilizer or inbuilt protection to voltage fluctuation/current surge.
4.4	**Power consumption**	Less than 50W
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Balance table with vibration bumpers suitable for granite or tile table top. External weights for calibration in absence of internal auto calibration.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of working in 50-100% humid condition and in temperature range of 5-40 degree Celsius.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Should be compatible with Medical grade disinfectant solutions like Cidex or hydrogen peroxide solution.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer ~~and Supplier~~ should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). ~~4. Shall meet IEC 60601-2-38 General Requirements of Safety for Medical Electrical Equipments part 2-38 Particular requirements for safety of Electrically Operated Hospital Beds~~ ~~Electromagnetic Compatibility.~~ ~~5. The manufacturer must have a management system certified to ISO 9001.~~ 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Not required.
8.2	**Requirements for sign-off**	Compliance with quantity checklist, Quality checks of the product and certificate from Legal Meteorology department.
8.3	**Training of staff (medical, paramedical, technicians)**	Hands on training to be provided to healthcare professional on using weighing scale, day to day maintenance/cleaning. Hand on training for in-house (Biomedical engineers) preventive/corrective maintenance (hardware/software).
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration or State/UT may also include the

		medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	One copy (hardcopy and softcopy) to be provided on user manual/operating manual and service/Technical manual
10.2	**Other accompanying documents**	Certification Documents implying compliance to standards and from Legal Meteorology department on weighing machine.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2Any Contract(AMC/CMC/add-hoc)rate available to be declared by the manufacturer. Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms. 3.Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed on weighing scale.

Measuring Jar- liquid

Version no. :	Draft_1
Date:	03/09/2018
Done by : (name.institution)	HCT/NHSRC

NAME, CATEGORY AND CODING		
UMDNS name		15586
UMDNS code(s)		jars
GENERAL		
1. USE		
1.1	**Clinical purpose**	These Jars are suitable for analysing quantity of alcohol, body fluid, biological specimen from stomach or bladder etc. in cadaver.
1.2	**Used by clinical department/ward**	Postmortem Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	~~Measuring Jar is made of stainless steel 202 grade.~~ 1.These autoclavable jugs must have excellent transparency and good chemical resistance. 2.These jugs are provided with a handle for easy & convenient lifting and neatly raised graduations for accurate reading. 3.~~Suitable for dispensing liquid and dry medications.~~ Strong, flexible cups measure grams~~, fluid ounces~~ and mL's~~, and cc's~~. The translucent jar should have lips/mouths. ~~4.Translucent jar should have with lip raised graduations on the outside of the cup.~~ 4. There should be 5 Jars each capable of measuring 50 ml, 100ml, 250ml,500ml, 1Liter.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication(where ever required**	Not required.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	50ml, 100ml,250ml,500ml and 1L.
3.2	**Weight (lbs, kg)**	Less than 500grams.
3.3	**Noise (in dBA)**	Zero
3.4	**Heat dissipation**	Zero
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	Zero
4.2	**Battery operated**	Not required
4.3	**Protection**	Not required
4.4	**Power consumption**	Zero
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	~~Balance table with vibration bumpers, preferably granite isolator.~~
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of working in 50-100% humid condition and in temperature range of 5-40 degree Celsius.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Should be compatible with Medical grade disinfectant solutions like Cidex or hydrogen peroxide solution.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Not required
8.2	**Requirements for sign-off**	Compliance with quantity checklist and Quality checks of the product
8.3	**Training of staff (medical, paramedical, technicians)**	Hands on training to be provided to healthcare professional on using measuring jar, day to day maintenance/cleaning.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1 year warranty or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	One copy (hardcopy and softcopy) to be provided on user manual/operating manual and service/Technical manual
10.2	**Other accompanying documents**	Not required
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc)rate available to be declared by the manufacturer. Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms.
11.2	**Recommendations or warnings**	Any warning sign would be adequaetly displayed.

Post Mortem Personal Protectives (Aprons, Gloves, Goggles, Boots, Mask)

Version no. :		Draft_1
Date:		03/09/2018
Done by : (name. institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Surgical Apron, Goggles, Boots, personnel protection mask.
UMDNS code(s)		27453,3104,34043,10301.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To provide personnel protection to surgeon /healthcare professional from spills & spatters during autopsy.
1.2	**Used by clinical department/ward**	Post-mortem Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Surgical Apron (1 Quantity per healthcare professional) i. Fluid penetration resistance- Should be made of polyethylene or polypropylene. ii. Reusable. iii. Washable using hand or machine. iv. Long-sleeved, cuffed apron Gloves (1 Box of minimum 50 units) i. BIS specifications gloves (IS 13422), surgical rubber made of Hypoallergic latex. ii. sterilised by Gamma Radiation / ETO. iii. Highly durable with smooth surface iv. Full fingered wear type with long sleeve. v. Colour: Orange, White, Cream white. Goggles (1 Quantity per healthcare professional) i. Should be Scratch resistant ii. Should be of Polycarbonate single-lens glasses Built-in iii. Should have Side shields Eyebrows protection Boots (1 Quantity per healthcare professional) i. Should be made of PVC-Nitrile rubber ii. Should be puncture-resistant sole, anti-static, high flexibility even at low temperatures. Non-slip, oil and grease resistant. iii. Should be unisex and washable. Mask (1 Box of minimum 50 units) I. Should be facial surgical mask. ii should have outer layer: polypropylene non-woven fabric-like, middle layer / filter: meltblown and outer layer: polypropylene non-woven.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication(where ever required**	Not required
3. PHYSICAL CHARACTERISTICS		

3.1	Dimensions(metric)	All sizes.
3.2	Weight (lbs, kg)	Not required.
3.3	Noise (in dBA)	Zero
3.4	Heat dissipation	Zero
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Zero
4.2	Battery operated	Not required.
4.3	Protection	Not required
4.4	Power consumption	Not required
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	~~Balance table with vibration bumpers, preferably granite isolator.~~
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	Capable of working in 50-100% humid condition and in temperature range of 5-40 degree Celsius.
6.2	User's care, Cleaning, Disinfection & Sterility issues	All reusable items should be compatible with Medical grade disinfectant solutions like Cidex or hydrogen peroxide solution. Easy to wash or autoclave (As per manufacture instructions on products)
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1.The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Not required
8.2	Requirements for sign-off	Compliance to quality parameters and quantity.
8.3	Training of staff (medical, paramedical, technicians)	Hands on training to be provided to healthcare professional on using measuring jar, day to day maintenance/cleaning.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1 year
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	One copy (hardcopy and softcopy) to be provided on user manual/operating manual.
10.2	Other accompanying documents	Not required.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.

	number)	Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

Spot Light

Version no. :		Draft_1
Date:		03/09/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Spot light, High Intensity
UMDNS code(s)		26899
GENERAL		
1. USE		
1.1	**Clinical purpose**	Spot lights used to illuminate cadaver for autopsy purpose..
1.2	**Used by clinical department/ward**	Post mortem Department.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Source of Light: LED light 2) Minimum 160,000-140,000 Lux at a working distance of 0.5m 3) Height adjustment: ≤440mm and colour rendering (Ra 98). 4) Radial and axial movement of the lamp. 5) Stable construction and manoeuvrable. 6) Water proof/splash proof. 7) Wheel should have brake.
2.2	**User's interface**	Manual using touch screen or buttons/switches.
2.3	**Software and/ or standard of communication(where ever required**	Not required
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	Minimum 7 feet in length.
3.2	**Weight (lbs, kg)**	Less than 150Kg
3.3	**Noise (in dBA)**	Noise pressure level: ≤60 dbA.
3.4	**Heat dissipation**	Not required.
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	Nominal 230V AC/ 50 Hz/1 phase.
4.2	**Battery operated**	Yes, To least for at least 2 hour with sealed batteries
4.3	**Protection**	Should have voltage stabilizer and surge protection.
4.4	**Power consumption**	Less than 100W
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Not required.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust**	Capable of working in 50-100% humid condition and in temperature range of 5-40 degree Celsius.

	…)	
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	All reusable items should be compatible with Medical grade disinfectant solutions like Cidex or hydrogen peroxide solution. Easy to wash or autoclave (As per manufacture instructions on products)
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed. 3. Manufacturer should have ISO 13485 certification for quality standards. 4. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Power supply 230V AC/50Hz/1 Phase
8.2	**Requirements for sign-off**	Compliance with quantity checklist, Quality check of the product.
8.3	**Training of staff (medical, paramedical, technicians)**	1.Hands on training to be provided to healthcare professional on using table, day to day maintenance/cleaning. 2.Hand on training for in-house (Biomedical engineers) preventive/corrective maintenance (hardware/software).
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	One copy (hardcopy and softcopy) to be provided on user manual/operating manual and service/Technical manual.
10.2	**Other accompanying documents**	Certification on quality of stainless steel. Compliance with autopsy table standards or regulation.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc)rate available to be declared by the manufacturer. Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms. 3.Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed on equipment.