



# TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR **POSTMORTEM DEPARTMENT**

**Ministry of Health and Family Welfare  
Government of India**

# DISCLAIMER

**Please note the following points before using these technical specifications:**

The specifications are suggestive in nature. State may adopt/adapt them as per context specific needs. These specifications may be tailored appropriately by users according to the specific situation, especially:	
i.	Local standards and legislation; local regulations and conditions; languages; installation conditions, technological levels, electrical range, capacities, utility environment, clinical procedures, personnel (users) experience and other local specific conditions.
ii.	The number of accessories, consumables, spare parts and other components indicates usual and/or ideal number and is not a mandatory quantity. The user can determine this quantity according to a product's characteristics and frequency of use in the hospital.
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*We gratefully acknowledge the contributions made by consultants and officers in the NHM division of the MoHFW.*



प्रीति सूदन  
सचिव

**PREETI SUDAN**  
Secretary



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण विभाग  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Government of India  
Department of Health and Family Welfare  
Ministry of Health and Family Welfare

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### MESSAGE

Various pioneering and innovative initiatives are being taken up by Government of India through National Health Mission (NHM) to provide affordable and effective healthcare to Indian Citizens. Substantial investments in the NHM have been made to strengthen Public Health System in the country.

Identifying vital medical devices is a critical part of strengthening health infrastructure. However rapidly changing technologies, complexity associated with medical devices, ensuring quality, safety performance and high costs of procurement - all these make selection of appropriate and cost effective devices a challenging task.

To address this need, the Ministry of Health and Family welfare, Government of India under the aegis of NHM formulated technical specifications of various medical devices as per Indian Public Health Standards. Cost, utility, availability in domestic market, maintenance and patient safety are crucial issues to be considered while procuring medical devices. I am delighted to note that these have been effectively considered by NHSRC under MoHFW while preparing the specifications.

Effort has been made to make the specifications as generic as possible and this has been the corner stone of this technical exercise. State may make appropriate modifications to suit their context specific requirements.

  
(Preeti Sudan)



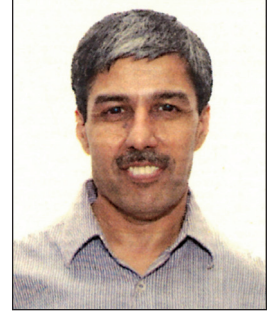


**मनोज झालानी**  
**Manoj Jhalani**

अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)  
Additional Secretary & Mission Director (NHM)



भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली - 110011  
GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN, NEW DELHI - 110011



## MESSAGE

National Health Mission is unique in such programmatic intervention envisioned at enrich largely on health with distinctive attention in vitalizing rural health infrastructure and services. Providing vital medical devices is a critical component of strengthening the health infrastructure.

Technical specifications play an important role in identification and procurement of appropriate cost effective medical devices. Factors to be considered include the type of health facility where the devices are to be used, the health work force available and the burden of disease experienced in the specific catchment area.

I am happy to note that, National Health System Resource Centre has filled an important technical gap by providing these specifications. The experts consulted for specification formulation exercises include experts from prestigious institutions such as AIIMS, PGIMER - Chandigarh, Ram Manohar Lohia Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, JIPMER, Hindustan Life Care Limited, Representatives from various state medical corporations to name a few. The specifications were also reviewed by Directorate General Health Services, Govt of India.

I am anticipating that using them as reference specifications while undertaking procurement will diminish costs of procurement, ensure the quality, standards, optimal performance of medical devices and reduce the procurement lead time. I am sure that technical specifications suggested here will serve as a reference for procurement of medical devices under the National Health Mission.

(Manoj Jhalani)

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**स्वच्छ भारत—स्वस्थ भारत**

Telefax : 23063687, 23063693 E-mail : manoj.jhalani@nic.in



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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. :		Ver.-1
Date:		03/09/2018
Done by : (Name/Institution)		HCT/NHSRC
<b>NAME, CATEGORY AND CODING</b>		
UMDNS name		Autopsy Tables
UMDNS code(s)		5246
<b>GENERAL</b>		
<b>1. USE</b>		
1.1	Clinical purpose	These tables are used for post-mortem examination and for demonstration purposes.
1.2	Used by clinical department/ward	Postmortem Department
<b>TECHNICAL</b>		
<b>2. TECHNICAL CHARACTERISTICS</b>		
2.1	Technical Characteristics	<ol style="list-style-type: none"> <li>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.</li> <li>2. Elevating height 32" to 40' up and down pedestal control. All thick gauge heavy duty anti corrosion stainless (SS 304) construction.</li> <li>3. Table top and integrated sink fabricate of minimum 14 gauge stainless steel, anti corrosion pedestal of minimum 11" gauge stainless steel with satin finish. Minimum 1/2" removable perforated grid plate with 3/8" diameter hole on 2" centers (4 each).</li> <li>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. Hydro aspirator with reverse flow having built in vacuum breaker. Access panel 2 outlet curved molded sides of table (Stainless Steel).</li> <li>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, molded and raised. Electrical outlets should be water splash proof.</li> <li>6. Table should be able to mount in position that allow surgeon to move around the table.</li> <li>7. Table should have engraved scale for cadaver measurement in centimeters and inches.</li> <li>8. Rivets or bolts on table should not enable bacterial or microorganism growth or accumulation.</li> </ol>
2.2	User's interface	Table should be height adjustable.
2.3	Software and/or standard of communication(where ever required)	Not required
<b>3. PHYSICAL CHARACTERISTICS</b>		
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.
<b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b>		
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.
<b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>		
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.
<b>BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS</b>		
<b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>		
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.
<b>7. STANDARDS AND SAFETY</b>		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	<ol style="list-style-type: none"> <li>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).</li> <li>2. Manufacturer should have ISO 13485 certification for quality standards.</li> <li>3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).</li> <li>4. Comply with IS 7036 autopsy table..</li> <li>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.</li> </ol>
<b>8. TRAINING AND INSTALLATION</b>		
8.1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Compliance with quantity checklist, Quality check of the product.

8.3	Training of staff (medical, paramedical, technicians)	<ol style="list-style-type: none"> <li>1. Hands on training to be provided to healthcare professional on using table, day to day maintenance/cleaning.</li> <li>2. Hand on training for in-house (Biomedical engineers) preventive/ corrective maintenance (hardware/ software).</li> </ol>
<b>9. WARRANTY AND MAINTENANCE</b>		
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.
<b>10. DOCUMENTATION</b>		
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	<ol style="list-style-type: none"> <li>1. Certification on quality of stainless steel. Compliance with autopsy table standards or regulation.</li> <li>2. Document illustrating frequency of calibration or preventive maintenance by manufacturer.</li> </ol>
<b>11. Notes</b>		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	<ol style="list-style-type: none"> <li>1. Contact details of manufacturer, supplier and local service agent to be provided;</li> <li>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.</li> <li>3. Manufacturer/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.</li> </ol>
11.2	Recommendations or warnings	Any warning sign would be adequately displayed on autopsy table.

# POST-MORTEM EQUIPMENT SET

Version no. :		Ver.-1
Date:		03/09/2018
Done by : (Name/institution)		HCT/NHSRC
<b>NAME, CATEGORY AND CODING</b>		
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
<b>GENERAL</b>		
<b>1. USE</b>		
1.1	Clinical purpose	Post mortem instruments for autopsy surgeon 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
<b>TECHNICAL</b>		
<b>2. TECHNICAL CHARACTERISTICS</b>		
2.1	List of instruments	<ol style="list-style-type: none"> <li>1. Amputation Saw 12" - 1 Quantity</li> <li>2. Bowel Scissors 7" - 4 Quantity</li> <li>3. Post Mortem Scissors 6" - 4 Quantity</li> <li>4. Blow Pipe straight 8" - 2 Quantity</li> <li>5. Hammer with chisel 8" - 1 Quantity</li> <li>6. Detachable Cross handle chisel 3.5" - 1 Quantity</li> <li>7. Skull Rest 7" - 1 Quantity</li> <li>8. Brain Knife 9.5" - 1 Quantity</li> <li>9. Caltin Knife 9.5" - 1 Quantity</li> <li>10. Cartilage Knife 7.5" - 1 Quantity</li> <li>11. Scalpel 16" - 4 Quantity</li> <li>12. Dissecting Forceps 6" - 1 Quantity</li> <li>13. Chain hook set of 3, 3" - 1 Quantity</li> <li>14. Scalpel Handle 127 mm - 1 Quantity</li> <li>15. Organ knife and saw 22mm blade - 1 Quantity</li> <li>16. Bistoury Knife 70mm blade - 1 Quantity</li> <li>17. Rib Knife - 1 Quantity</li> <li>18. Pelvic Organ Knife - 1 Quantity</li> <li>19. Dissection scissors - 1 Quantity</li> <li>20. Bone cutting scissors - 1 Quantity</li> <li>21. Needle Holder - 1 Quantity</li> <li>22. Raspatory - 1 Quantity</li> <li>23. Retractor - 2 Quantity</li> <li>24. Osteotome - 2 Quantity</li> <li>25. Vagotome - 1 Quantity</li> <li>26. Surgical needles - 12 Quantity</li> <li>27. Folding rulers 300 mm - 2 Quantity</li> <li>28. Probes with eye/fish tail - 2 Quantity</li> <li>29. Measuring/specimen jar (100 ml and 1 Litre) - 1 Quantity</li> <li>30. Rib Shears</li> </ol>
2.2	User's interface	All knives should have stainless steel handle and surgical quality.

2.3	Software and/or standard of communication(where ever required)	Not required
<b>3. PHYSICAL CHARACTERISTICS</b>		
3.1	Dimensions(metric)	As specified in IS/ISO standards.
3.2	Weight (lbs, kg)	As specified in IS/ISO standards.
3.3	Noise (in dBA)	Zero
3.4	Heat dissipation	Zero
3.5	Mobility, portability	Portable
<b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b>		
4.1	Power requirements	Zero
4.2	Battery operated	Zero
4.3	Protection	Not required.
4.4	Power consumption	Zero
<b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>		
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.
<b>BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS</b>		
<b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>		
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	<ol style="list-style-type: none"> <li>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.</li> <li>2. Should be compatible with Medical grade disinfectant solutions like Cidex or hydrogen peroxide solution.</li> </ol>
<b>7. STANDARDS AND SAFETY</b>		
7.1	Certificates (pre-market, sanitary,...); Performance and safety standards (specific to the device type); Local and/or international	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> </ol>

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)	<ol style="list-style-type: none"> <li>1. Contact details of manufacturer, supplier and local service agent to be provided;</li> <li>2. Any Contract(AMC/CMC/add-hoc) rate available to be declared by the manufacturer.</li> <li>3. Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms.</li> <li>4. manufacturer/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.</li> </ol>
11.2	Recommendations or warnings	Any warning sign would be adequately displayed on each instrument.

# AUTOPSY WEIGHING MACHINE – ORGAN

Version no. :		Ver.-1
Date:		03/09/2018
Done by : (Name/Institution)		HCT/NHSRC
<b>NAME, CATEGORY AND CODING</b>		
UMDNS name		Autopsy scale
UMDNS code(s)		5612
<b>GENERAL</b>		
<b>1. USE</b>		
1.1	Clinical purpose	Stainless steel scales capable to measure the weight of an organ.
1.2	Used by clinical department/ward	Postmortem Department
<b>TECHNICAL</b>		
<b>2. TECHNICAL CHARACTERISTICS</b>		
2.1	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> <li>Capacity: 0 - 20 Kg with Accuracy of 1 gram.</li> <li>Building: Stainless Steel housing.</li> <li>Display: 6 digits LCD .</li> <li>Function like Gross Weight - Net Weight - Tare - Auto-zero should be available.</li> <li>Stainless steel weighing pan, approximately 80 mm diameter.</li> <li>Waterproof display and keypad, sealed by a durable flexible membrane.</li> <li>Background illuminated (backlit) display with digits at least 15 mm high.</li> <li>Level indicator in the view field of the display.</li> <li>Built-in motorized calibration of weight with automatic adjustment (or calibration using an external standard weight).</li> <li>Readability: 0.0001 g (0.1 mg).</li> <li>Repeatability: 0.0001 g (0.1 mg).</li> <li>Linearity: 0.0002 g (0.2 mg).</li> </ol>
2.2	User's interface	Manual, English Menu
2.3	Software and/or standard of communication(where ever required)	Inbuilt
<b>3. PHYSICAL CHARACTERISTICS</b>		
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
<b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b>		
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/Ambiance (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	<ol style="list-style-type: none"> <li>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).</li> <li>2. Manufacturer should have ISO 13485 certification for quality standards.</li> <li>3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).</li> <li>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.</li> </ol>
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)	<ol style="list-style-type: none"> <li>1. Hands on training to be provided to healthcare professional on using weighing scale, day to day maintenance/cleaning.</li> <li>2. Hand on training for in-house (Biomedical engineers) preventive/ corrective maintenance (hardware/software).</li> </ol>
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 (hard copy and soft copy) 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)	<ol style="list-style-type: none"> <li>1. Contact details of manufacturer, supplier and local service agent to be provided;</li> <li>2. Any Contract(AMC/CMC/add-hoc)rate available to be declared by the manufacturer.</li> <li>3. Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms.</li> <li>4. Manufacturer/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.</li> </ol>
11.2	Recommendations or warnings	Any warning sign would be adequately displayed on weighing scale.

# MEASURING JAR- LIQUID

Version no. :		Ver.-1
Date:		03/09/2018
Done by : (Name/Institution)		HCT/NHSRC
<b>NAME, CATEGORY AND CODING</b>		
UMDNS name		15586
UMDNS code(s)		Jars
<b>GENERAL</b>		
<b>1. USE</b>		
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
<b>TECHNICAL</b>		
<b>2. TECHNICAL CHARACTERISTICS</b>		
2.1	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> <li>1. These autoclavable jugs must have excellent transparency and good chemical resistance.</li> <li>2. These jugs are provided with a handle for easy &amp; convenient lifting and neatly raised graduations for accurate reading. Strong, flexible cups measure grams and mL's. The translucent jar should have lips/mouths.</li> <li>3. There should be 5 Jars each capable of measuring 50ml, 100ml, 250ml, 500ml, 1Liter.</li> </ol>
2.2	User's interface	Manual
2.3	Software and/or standard of communication(where ever required)	Not required.
<b>3. PHYSICAL CHARACTERISTICS</b>		
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
<b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b>		
4.1	Power requirements	Zero
4.2	Battery operated	Not required
4.3	Protection	Not required
4.4	Power consumption	Zero
<b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	

<b>BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS</b>		
<b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>		
6.1	Atmosphere/Ambiance (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.
<b>7. STANDARDS AND SAFETY</b>		
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.
<b>8. TRAINING AND INSTALLATION</b>		
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.
<b>9. WARRANTY AND MAINTENANCE</b>		
9.1	Warranty	1 year warranty or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
<b>10. DOCUMENTATION</b>		
10.1	Operating manuals, set manuals, other manuals	One copy (hard copy and soft copy) to be provided on user manual/ operating manual and service/Technical manual
10.2	Other accompanying documents	Not required
<b>11. Notes</b>		
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.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

# POST MORTEM PERSONAL PROTECTIVES (APRONS, GLOVES, GOGGLES, BOOTS, MASK)

Version no. :		Ver.-1
Date:		03/09/2018
Done by : (Name/Institution)		HCT/NHSRC
<b>NAME, CATEGORY AND CODING</b>		
UMDNS name		Surgical Apron, Goggles, Boots, personnel protection mask.
UMDNS code(s)		27453,3104,34043,10301.
<b>GENERAL</b>		
<b>1. USE</b>		
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
<b>TECHNICAL</b>		
<b>2. TECHNICAL CHARACTERISTICS</b>		
2.1	Technical characteristics (specific to this type of device)	<p><b>Surgical Apron (1 Quantity per healthcare professional)</b></p> <ul style="list-style-type: none"> <li>i. Fluid penetration resistance- Should be made of polyethylene or polypropylene.</li> <li>ii. Reusable.</li> <li>iii. Washable using hand or machine.</li> <li>iv. Long-sleeved, cuffed apron</li> </ul> <p><b>Gloves (1 Box of minimum 50 units)</b></p> <ul style="list-style-type: none"> <li>i. BIS specifications gloves (IS 13422), surgical rubber made of Hypoallergic latex.</li> <li>ii. Sterilised by Gamma Radiation / ETO.</li> <li>iii. Highly durable with smooth surface</li> <li>iv. Full fingered wear type with long sleeve.</li> <li>v. Colour: Orange, White, Cream white.</li> </ul> <p><b>Goggles (1 Quantity per healthcare professional)</b></p> <ul style="list-style-type: none"> <li>i. Should be Scratch resistant</li> <li>ii. Should be of Polycarbonate single-lens glasses Built-in</li> <li>iii. Should have Side shields Eyebrows protection</li> </ul> <p><b>Boots (1 Quantity per healthcare professional)</b></p> <ul style="list-style-type: none"> <li>i. Should be made of PVC-Nitrile rubber</li> <li>ii. Should be puncture-resistant sole, anti-static, high flexibility even at low temperatures. Non-slip, oil and grease resistant.</li> <li>iii. Should be unisex and washable.</li> </ul> <p><b>Mask (1 Box of minimum 50 units)</b></p> <ul style="list-style-type: none"> <li>i. Should be facial surgical mask.</li> <li>ii. should have outer layer: polypropylene non-woven fabric-like, middle layer / filter: melt blown and outer layer: polypropylene non-woven.</li> </ul>
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)	
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (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 manufacturer 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	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 (hard copy and soft copy) 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 number)	<ol style="list-style-type: none"> <li>1. Contact details of manufacturer, supplier and local service agent to be provided;</li> <li>2. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.</li> <li>3. Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms.</li> </ol>
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

# SPOT LIGHT

Version no. :		Ver.-1
Date:		03/09/2018
Done by : (Name/Institution)		HCT/NHSRC
<b>NAME, CATEGORY AND CODING</b>		
UMDNS name		Spot light, High Intensity
UMDNS code(s)		26899
<b>GENERAL</b>		
<b>1. USE</b>		
1.1	Clinical purpose	Spot lights used to illuminate cadaver for autopsy purpose.
1.2	Used by clinical department/ward	Post mortem Department.
<b>TECHNICAL</b>		
<b>2. TECHNICAL CHARACTERISTICS</b>		
2.1	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> <li>1. Source of Light: LED light</li> <li>2. Minimum 160,000-140,000 Lux at a working distance of 0.5m</li> <li>3. Height adjustment: ≤440mm and colour rendering (Ra 98).</li> <li>4. Radial and axial movement of the lamp.</li> <li>5. Stable construction and maneuverable.</li> <li>6. Water proof/splash proof.</li> <li>7. Wheel should have brake.</li> </ol>
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
<b>3. PHYSICAL CHARACTERISTICS</b>		
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
<b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b>		
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
<b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Not required.
<b>BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS</b>		
<b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>		
6.1	Atmosphere/Ambiance (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 manufacturer instructions on products)
<b>7. STANDARDS AND SAFETY</b>		
7.1	Certificates (pre-market, sanitary,...); Performance and safety standards (specific to the device type); Local and/or international	<ol style="list-style-type: none"> <li>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).</li> <li>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.</li> <li>3. Manufacturer should have ISO 13485 certification for quality standards.</li> <li>4. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).</li> </ol>
<b>8. TRAINING AND INSTALLATION</b>		
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)	<ol style="list-style-type: none"> <li>1. Hands on training to be provided to healthcare professional on using table, day to day maintenance/cleaning.</li> <li>2. Hand on training for in-house (Biomedical engineers) preventive/corrective maintenance (hardware/software).</li> </ol>
<b>9. WARRANTY AND MAINTENANCE</b>		
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.
<b>10. DOCUMENTATION</b>		
10.1	Operating manuals, set manuals, other manuals	One copy (hard copy and soft copy) 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.
<b>11. Notes</b>		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	<ol style="list-style-type: none"> <li>1. Contact details of manufacturer, supplier and local service agent to be provided;</li> <li>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.</li> <li>3. Manufacturer/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.</li> </ol>
11.2	Recommendations or warnings	Any warning sign would be adequately displayed on equipment.



## LIST OF CONTRIBUTORS

OVERALL LEADERSHIP AND GUIDANCE			
S.NO	EXPERTS	DESIGNATION	ORGANIZATION
1	Mr Manoj Jhalani	Additional Secretary,	Ministry of Health and Family Welfare, Government of India
2	Dr Manohar Agnani	Joint Secretary (Policy)	Ministry of Health and Family Welfare, Government of India
3	Dr Rajani R. Ved	Executive Director	National Health System Resource Centre (NHSRC),
4	Mr. N. Yuvraj	Dy. Secretary	Ministry of Health and Family Welfare, Government of India
TECHNICAL EXPERTS			
S.NO	EXPERTS	DESIGNATION	ORGANIZATION
1	Dr. Arvind Kumar	Professor Forensic Medicine	LHMC Delhi
2	Dr. MK Wahi	Professor & HOD Forensic Medicine	Safdarjung VMMC Delhi
3	Dr. Shalini Girdhan	Associate Professor Forensic Medicine	PGI & RML
4	Dr. Gaurav V. Jain	Professor Forensic Medicine & Toxicology Department	Safdarjung VMMC Delhi
5	Dr. Bijay Kumar Dhal	M.O (Equipment)	OSMCL, Odisha
6	Er. Prakash Mallick	Biomedical Engineer-State Drug Management Unit	DHS, Odisha
INDUSTRY ASSOCIATION			
1	Representatives from HLL- HITES		
2	Representatives from Indian Pharmacopoeia Commission (IPC)		
3	Representatives from Federation of Indian Chambers of Commerce & Industry (FICCI) Association.		
4	Representatives from Medical Technology Association of India (MTAI) Association.		
5	Representatives from Association of Indian Medical Device Industry (AIMED) Association.		
INTERNAL EXPERTS			
1	Dr. S.B. Sinha	Ex- Advisor - Healthcare Technologies	NHSRC, New Delhi
2	Er. Mohammed Ameer	Senior Consultant- Healthcare Technologies	NHSRC, New Delhi
3	Er. P. S. Vigneshwaran	Consultant- Healthcare Technologies	NHSRC, New Delhi

4	Er. Anjaney	Consultant- Healthcare Technologies	NHSRC, New Delhi
5	Er. Ajai Basil	Consultant- Healthcare Technologies	NHSRC, New Delhi
6	Er. Bharat Bhushan Dahiya	Consultant- Healthcare Technologies	NHSRC, New Delhi
7	Er. Vertika Agarwal	Consultant- Healthcare Technologies	NHSRC, New Delhi
8	Er. Pawan Kumar	Fellow- Healthcare Technologies	NHSRC, New Delhi
9	Er. Purnima Dhamija	Fellow- Healthcare Technologies	NHSRC, New Delhi

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