Selling Used Medical Equipment

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What is Medical/Scientific Equipment?

• Equipment used in a medical or scientific lab
• Equipment used to treat patients
  • Human
  • Animal
Ask a Doctor what Medical Equipment is

The Student doesn’t know;

The doctor doesn’t care

The Professor expects us to figure it out;

The Nobel Prize winner can’t be bothered
What is unique about used Medical or Scientific Equipment?

- It can hurt you
- It can hurt someone else
- It can be used for bad purposes
Initial Issues at the end of Useful Life of Medical Equipment

- What is this thing?
- What has been in it or on it?
- Is it or has it been contaminated with viral, chemical or biological/radiological particles
- How do we know it is clean and safe to pick up as surplus equipment?
Safety of handling Used Medical Equipment

“We are picking it up at a medical facility, so it is clean and free from contamination”

“Medical personnel are responsible for saving lives so bacteriological and nuclear sources have been removed”
Safe Handling of Used Medical Equipment

• We are picking it up at a medical facility, so surely it is clean and free from contamination

• Medical personnel are responsible for saving lives so surely bacteriological and nuclear sources have been removed

Right!
You bet your life!

2014 NPMA Fall Educational Training Seminar
Safety in the Handling of Used Medical Equipment

Infectious Diseases
• Staff infections
• MRSA

Picked up in a medical facility

Staff Infection

Staff Infection

Photo Credit: Gregory Moran, M.D.
How do Surplus Warehouse personnel know it is safe to pick up?
How do the Surplus Warehouse personnel know it is safe to pick up?

- **Policy/Procedure:**

  - Anything that was contaminated must have a Decontamination Certification attached.
  
  - Anything that looks like it could have been contaminated should have a Decontamination Certification attached.
Are we only concerned about Medical Equipment?

No!

– Refrigerators of all sizes, makes and models are used for holding very serious experimental materials
– Ovens/heaters/stoves are used to make contaminates
– Almost anything coming out of a lab could have been contaminated
Regulations

- 40 CFR – Hazardous Wastes
- 29 CFR – Bloodborne Pathogens
- 42, 7, and 9 CFR – Select Agent and Toxin
- 21 CFR – Controlled Substances
- 6 CFR – Chemicals of Interest
- NIH Guidelines
Decontamination Form

“For the unit identified above, I certify by my signature in the table below that the following tasks have been completed in accordance with applicable policy, procedure, and guidance provided by EH&S staff:

• All hazardous contents, if any, have been removed and properly disposed of or stored.
Decontamination Form (Continued)

- All surfaces, interior and exterior, are free from removable dust, dirt and debris.
- All surfaces, interior and exterior, were decontaminated as indicated on the Method table below.”

Method of Decontamination

• The unit is a BioSafety Cabinet. It was decontaminated by a vendor using an EH&S approved method. A copy of the certification provided by the vendor is attached (stapled).

or
Method of Decontamination

The unit is not a BioSafety Cabinet but was used in a BSL3 laboratory. The unit was decontaminated by the method checked below:

- Extensive disinfectant decontamination with ____________________________

- The unit was decontaminated by a vendor using and EH&S-approved method. I have attached (stapled) a copy of the certification provided by the vendor.

or
Method of Decontamination

The unit is not a BioSafety Cabinet and was not used in a BSL3 laboratory. All surfaces, interior and exterior, were decontaminated by wiping with the chemical checked below:

- € Wescodyne (idophor)
- € Concentrated Lysol (phenolic)
- € 10% Chlorine Bleach (sodium hypochlorite)
- Other
I am a member of the EH&S Bio/Chem Safety group. I have spoken with the person signing the certification above and I have inspected the unit in question. I believe the work has been completed as described and the unit looks safe to move.

- Printed Name
- Copy Protection Signature on Sticker
- Must match signature on file with Inventory Control
- Date
OK, I get it! Things that can be contaminated are what we need to be concerned about

- Not all!
  - There is medical equipment that operate with nuclear sources. The nuclear source must be removed
  - Certain Laser devices are on a national registry and have to be tracked as location or ownership change
Disposal Restrictions

• What are our legal liabilities if we sell it or scrap it?
• Are there legal restrictions on the transfer of the asset either through sale or salvage?
• Are there licenses required for a buyer or salvage yard to have the item?
What can we sell?
Who can we sell it to?
Each State has rules

The State of Texas defines a medical device “as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component; part, or accessory that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals” (TAC 229.630)
Is it a Medical Device?

When trying to decide if it’s a medical device or not consider its “intended function”.

Extensive medical device database at CFDA Center for Devices and Radiological Health (CDRH) for product classification.
“But I don’t work at a Medical University”

Aside from the obvious places like physician’s offices, clinics, surgery centers, hospitals, medical schools, etc., you’ll find them in student health centers in public schools, training classrooms, academic branches of Universities, laboratories, airports, aboard aircraft, in City EMS vehicles and many of other locations.
So, what are the rules?

The rules are somewhat different for “Used” Medical equipment then for “Distressed” Medical Equipment.
Used Medical Equipment vs. Distressed Medical Equipment
Distressed Medical Devices

Distressed device - Any device that is adulterated or misbranded within the meaning of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §§431.111 and 431.112. The term includes a device that:

(A) has lost its labeling or is otherwise unidentified;
Distressed Medical Devices

**Distressed device** - Any device that is adulterated or misbranded within the meaning of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §§431.111 and 431.112. The term includes a device that:

(B) has been subjected to prolonged or improper storage, including unsanitary conditions whereby the device may have been contaminated with filth or whereby it may have been rendered injurious to health;
Distressed Medical Devices

**Distressed device** - Any device that is adulterated or misbranded within the meaning of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §§431.111 and 431.112. The term includes a device that:

(C) has been subjected for any reason to abnormal environmental conditions, including temperature extremes, humidity, smoke, water, fumes, pressure, or radiation;
Distressed Medical Devices

**Distressed device** - Any device that is adulterated or misbranded within the meaning of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §§431.111 and 431.112. The term includes a device that:

(d) has been subjected to conditions that result in strength, purity, or quality falling below that which it purports or is represented to possess
Distressed Medical Devices

Distressed device - Any device that is adulterated or misbranded within the meaning of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §§431.111 and 431.112. The term includes a device that:

(E) or, may have been rendered unsafe or unsuitable for its intended use according to the manufacturer’s recommendations or specifications; or for any reason other than those specified by this paragraph.
Oh my! How do I know if it “distressed”? 

- Generally, everything turned into the surplus warehouse is best considered distressed.
- Items sold direct are usually “Used.”
Why do I care if it is “Distressed or Used”? 

- Liability
- Value
Why do I care if it is “Distressed or Used”?

The State of Texas regulates the sale of “distressed” medical devices within the state and requires purchasers to possess one of two types of device salvage licenses:

- Medical Device Salvage Broker License
- Medical Device Salvage Establishment License
Exempt from Licensure are:

- Purchaser from out of state (must comply with own state laws)
- Manufacturer or Distributor
- Auctioneer
- Equipment is certified to be “Used”
Other Considerations When Selling Medical Devices

- Overlapping Equipment Categories – e.g. Lab equipment, in-vitro diagnostic equipment, radiation emitting devices. Each may have it’s own statutory requirements for sale or transfer in addition.

- HIPAA, Patient Health Information (PHI). Equipment stores patient data.
Other Considerations When Selling Medical Devices

- Decontamination, physical inspection of equipment to avoid accidental release of drugs or other hazardous materials to the public.
- Unsalable equipment / scrap.
Other Considerations When Selling Medical Devices

- Is your buyer legally qualified to make the purchase?
Who Buys Used Medical Devices?

- End users including licensed practitioners. Even a physician needs a device salvage license to purchase “distressed” medical devices.
- Used medical equipment dealers, brokers, and exporters.
- Salvage buyers – for the material content of the equipment only.
Who Buys Used Medical Devices?

- Equipment can be donated to charitable organizations, but the donee may still require to be licensed.
- Buyers are global.
- What may be obsolete in the U.S. may still be usable abroad.
Why Sell Used Medical Equipment?

- Hospitals can operate on profit margins as low as 2-3%. Thus the sale of a used piece of equipment for $1,000.00 can be the equivalent of $35,000 to $50,000.00 in patient billing.

- Avoid carrying costs and loss of value of idle assets over time.
Why Sell Used Medical Equipment?

- Auctions offer a transparent marketplace and marketing advantages.

- Consider equipment trade-in offers, too.
It's QUESTION TIME!!