Regulatory Framework for Control of Refurbished Medical Devices

Alfred KWEK
Director, Regulatory Affairs, ASEAN
GE Healthcare
Presentation to APEC Workshop on Remanufactured Goods, Malaysia, 22 Oct 2012
$18B Broad Technology Portfolio

Diagnostic & Clinical Equipment
- Diagnostic Imaging
- Clinical Products
- Home Health

Information Tech. and Services
- Electronic Medical Records (EMR)
- Picture Archiving System (PACS)
- Clinical Knowledge solutions
- Equipment Service Solutions

Molecular Medicine
- Bio-process
- Protein & Cell Sciences
- Contrast Media
- Molecular Pathology
HEALTHCARE TOUCHES EVERYONE

healthymagination

imagination at work
Agenda

- What is a medical device?
- What is / not Refurbishment?
- Ensuring Safety of Medical Device Manufacturers
  - Quality Management System
  - Use of International Standards to Ensure Safety & Performance
- Ensuring Safety of Refurbished Medical Device
Medical Devices: Spare Parts for Ourselves

Devices for the body

- **Teeth**
  - Titanium implant for false teeth.

- **Shoulders**
  - People with severe pain in their shoulders, usually caused by arthritis, find relief with an artificial shoulder that gives them mobility without pain.

- **Breasts**
  - Silicon implants are used mainly for cosmetic reasons to augment breast size. But they can also be used to reconstruct a breast following its removal for breast cancer.

- **Heart**
  - A diseased or dysfunctional heart valve can be replaced with a mechanical one, to allow proper blood flow through the heart.
  - An implanted defibrillator, placed under the skin of patients at risk of sudden cardiac death, will jumpstart a heart that has stopped.

- **Spine**
  - Bone cement is used to hold up a vertebra that has collapsed because the bone has worn out. An artificial disc may be implanted instead.

- **Hips**
  - A hip replacement implant comes in metal, plastic or ceramic.

- **Knees**
  - An artificial knee joint can substitute for worn-out knees.

- **Reproductive organs**
  - **FOR MEN**
    - For erectile dysfunction, a penile implant, where a pair of malleable rods are surgically implanted within the erection chambers of the penis, helps to improve sex life.
  - **FOR WOMEN**
    - An intra-uterine device is inserted to prevent conception.

- **Abdomen**
  - People with kidney failure on peritoneal dialysis have a catheter inserted into their abdomens with part of it on the surface, so they can carry out the dialysis.

- **Stomach**
  - A lapband around the stomach, limiting the amount of food eaten to help obese patients lose weight.

- **Others**
  - Following an operation, surgeons need to close the wound. Removable or degradable sutures are used.
Examples of medical devices

Bandages
Gauge
IV Sets
Blood bags
Wheel Chair
Hospital bed
Examples of medical devices

- Non-medicating saline eye wash
- Examination gloves
- Contact lenses for long-term continuous use
- Tracheal tubes
Examples of active devices

Hearing aids
Baby incubator
CT Scanner
Electronic thermometer
Examples of implants and long term invasive devices

Prosthetic heart valves
Pacemaker
Stents
Breast implants
Definition – Medical Device

“medical device” shall mean any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article:

(a) intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:-

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
(iii) investigation, replacement, modification, or support of the anatomy or of a physiological process,
(iv) supporting or sustaining life,
(v) control of conception,
(vi) disinfection of medical devices,
(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
# Refurbishment versus Single Use

<table>
<thead>
<tr>
<th>Refurbishment</th>
<th>Single Use</th>
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<tbody>
<tr>
<td>Applies mainly to reusable devices.</td>
<td>Single use devices are, by definition, normally used in their original state, then discarded</td>
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Not every medical device is appropriate for refurbishment
Repair and Maintenance

It is common for a reusable medical device to require routine service and repair in order to maintain it in good and safe operating condition.

Such repair and maintenance may be carried out by the owner, the manufacturer or a third party.

Repair and maintenance is not refurbishment
Medical Device Regulatory Framework

Figure 6. Common stages of government regulations

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<td>Instructions for use</td>
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<td>Problem identification and alerts</td>
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REFURBISHED MEDICAL DEVICE:

a medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it:

- stripping into component parts or sub-assemblies;
- checking their suitability for reuse;
- replacement of components/sub-assemblies not suitable for reuse;
- assembly of the reclaimed and/or replacement components/sub-assemblies;
- testing of the assembled device against either original or revised release criteria; or
- identifying an assembled medical device as a refurbished medical device.

Source: Annex 9 Labelling Requirements of the DRAFT ASEAN Medical Device Directive
GHTF* Definition of a Manufacturer

Any natural or legal person who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies)

*Global Harmonization Task Force
GHTF Definition of a Manufacturer

This natural or legal person has the **ultimate responsibility** for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold.

**Manufacturer’s responsibilities** described in other GHTF guidance documents – include pre- and post- marketing requirements (e.g., **vigilance reporting** and notification of field safety corrective actions).
GHTF Definition of a Manufacturer

Design and/or manufacture may include:-

• Specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilisation, installation, or remanufacturing; and/or

• Assembly, packaging, processing and/or labelling of one or more finished products
GHTF Definition of a Manufacturer

Any person who assembles or adapts a device(s) that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is **not** the **manufacturer**, provided the assembly or adaptation **does not change the intended use** of the device(s).
GHTF Definition of a Manufacturer

Any person who changes the intended use of, or modifies, a finished medical device in a way that may affect safety or performance, without acting on behalf of the original manufacturer and who makes it available for use under his own name should be considered the manufacturer of the modified medical device.
Parties Involved

**Authorised Refurbisher**
- Work with manufacturer specifications
- May include changes/upgrades
- Refurbishment done at request of original manufacturer and product re-sold by manufacturer

**3rd Party Refurbisher**
- Refurbish equipment without manufacturer’s authorization
- “Refurbished” device is placed on the market under the name of the person responsible for the refurbishment, without changing the intended use
- Person responsible for the refurbishment = new product owner

If the intended use/purpose of the device is changed after “refurbishment” it is a “new” medical device.
Ensuring Safety of New Devices
(non-exhaustive)
ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'Assurance Qualité / Approval of AuT Quality Assurance System
ANNEXE II point 3 Directive 93/42/EEC relative aux dispositifs médicaux
ANNEX II section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant (nom et adresse) / Manufacturer (name and address)
GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd,
WAUKESHA, WI 53188 UNITED STATES

Catégorie du(des) dispositif(s) / Device(s) category
Dispositif ou système de radiodiagnostic
Medical diagnostic radiology device or system

Le LNE/G-MED atteste qu’à l’examen des résultats figurant dans le rapport référencé M011885-R, le système d’assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l’annexe II point 3 de la Directive 93/42/EEC.
LNE/G-MED certifies that, on the basis of the results contained in the file referenced M011885-R, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II section 3

Début de validité / Effective date : December 21st, 2011 (included)
Valable jusqu’au / Expiry date : December 20th, 2014 (included)

For the General Director
Lawrence DEGALLIER
Deputy Director

Laboratoire national de métrologie et d’essais - Établissement public à caractère industriel et commercial
LNE/G-MED - Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr
EC Certificate

- EC Certificate
- Approval full Quality Assurance System
- Annex II section 3 Directive 93/42/EEC concerning medical devices
- Manufacturer
- GE Medical Systems, LLC – Waukesha, WI 53188, USA
- Device category
- Medical diagnostic radiology device or system
- G-Med certifies that, on the basis of the results contained in the file referenced M011885-R, the quality system – for design, manufacturing, and final inspection – of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II section 3.
What’s Does it Mean?

As an example

• What are the meanings behind the wordings of the certificate?

• Notified Body (CE XXXX) issues a certificate. It means that:-

  ➢ manufacturer has maintained a QMS that meets the ISO 13485:2003 standard;
  and
  ➢ meets **EU Medical Device Directive (93/42/EEC)**
Appareils électromédicaux –
Partie 1-1:
Règles générales de sécurité –
Norme collatérale: Règles de sécurité pour systèmes électromédicaux

Medical electrical equipment –
Part 1-1:
General requirements for safety –
Collateral standard: Safety requirements for medical electrical systems
EU Harmonized Standards (Ionizing Radiation Devices) (New)

EN 60601-1-3:2008
Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance -
Collateral Standard: Radiation protection in diagnostic Xray equipment
IEC 60601-1-3:2008
EU Harmonized Standards (Ionizing Radiation Devices) (Old)

EN 60601-1-3:1994

Medical electrical equipment -- Part 1: General requirements for safety -- 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:1994
Refurbishment
Principles of **Good Refurbishment Practices (GRP)**

*Refurbishment Definition*

“a **systematic** process that ensures safety and effectiveness of the medical equipment **without** significantly changing the equipment’s or system’s performance, safety specifications and/or changing **intended use as in its original registration**.”
Principles of **Good Refurbishment Practices (GRP)**

Any upgrades processed during GRP refurbishment shall be performed in a manner consistent with the **original product specifications** and **service procedures** defined by the **manufacturer** for that equipment or system.
Same Elements of Regulatory Control for MDs

✓ Quality Management System (QMS)
✓ Post-market Surveillance
✓ Technical Documentation
✓ Declaration of Conformity
✓ Registration of manufacturers, distributors and their devices
CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 7850 rev 4

Le LNE certifie que le système de management de la qualité développé par
LNE certifies that the quality management system developed by

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd,
WAUKESHA, WI 53188 UNITED STATES

pour les activités
for the activities

Conception, fabrication, contrôle final de dispositifs ou systèmes d’imagerie médicale.
Voir addendum
Design, manufacturing, final test of medical imaging devices or systems.
See addendum

réalisées sur le(s) site(s) de
performed on the location(s) of

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd - WAUKESHA, WI 53188 - UNITED STATES
GE MEDICAL SYSTEMS, LLC
3114 North Grandview Blvd - WAUKESHA, WI 53188 - UNITED STATES
GE MEDICAL SYSTEMS, LLC
4855 West Electric Avenue - MILWAUKEE, WI 53219 - UNITED STATES

est conforme aux exigences des normes internationales
complies with the requirements of the international standards


Début de validité / Effective date : December 21st, 2011 (included)
Valable jusqu’au / Expiry date : December 20th, 2014 (included)
Etabli le / Issued on : December 1st, 2011

For the General Director
Laurence DAGALLIER
Deputy Director
Résumé des activités couvertes par le certificat :
Summary of activities covered by the certificate :

French version :
Conception, fabrication, contrôle final de dispositifs ou systèmes de diagnostic tomodensitomètre par émission de positron, dispositifs ou systèmes de diagnostic X-Ray, dispositifs ou systèmes de diagnostic tomodensitomètres (scanners), gaines équipées (gaine + tube radiogène) et d'application logicielle.
Mise à disposition de dispositifs ou systèmes d'imagerie médicale d'occasion.

English version :
Design, manufacturing, final test of medical diagnostic positron emission tomography devices or systems, medical diagnostic X-Ray devices or systems, diagnostic computed tomography devices or systems, X-ray tube assembly (housing + tube) and software application.
Supply of pre-owned medical imaging devices or systems.

***********************************************************************************************************************************************

- LNE certifies that the QMS developed by GE Medical Systems, LLC – Waukesha, WI 53188, USA for the activities – Design, manufacturing, final test of medical imaging devices or systems performed on the location - GE Medical Systems, LLC – Waukesha, WI 53188, USA complies with the requirements of the international standard ISO 13485:2003

- Summary of activities covered by certificate
  - Design, manufacturing, final test of PET, X-Ray, X-Ray tube assembly and software applications
  - Supply of pre-owned medical imaging devices or systems

- The quality management system is subject to yearly surveillance audit.
List of Device Recalls

FDA posts consumer information about the most serious medical device recalls. These products are on the list because there is a reasonable chance that they could cause serious health problems or death.

Use the yearly lists to find information about Class I medical device recalls and some Class II and III recalls of interest to consumers. The links give details about what to do if you own or use one of these products.

Please note that FDA now lists medical device recall notices by the date that it posts the recall rather than the recall initiation date. You can find the date that a firm initiated a recall in the text of the recall notice.

### Recent Medical Device Recalls

Listed by date posted on FDA website.

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Date</th>
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<tbody>
<tr>
<td>Custom Medical Specialties, Inc., Custom HSG Tray, Hysteroscopic Sterilization Pack, Custom Vein Tray, Custom Amino Tray, Fox Chase Specials Pack, Abington Radiology Drainage Pack, Custom CT Biopsy Tray, HSG Tray, Custom Myelogram Tray, and Hysteroscopy Sterile Procedure Kit</td>
<td>09/25/12</td>
</tr>
<tr>
<td>I-Flow ON-Q Pump with ONDEMAND Bolus Button</td>
<td>08/31/12</td>
</tr>
<tr>
<td>Baxter Healthcare Corporation, Automix Automated Nutrition Compounder Systems</td>
<td>08/29/12</td>
</tr>
<tr>
<td>CareFusion Alaris Pump Module, Model 8100 – Motor Stall</td>
<td>08/23/12</td>
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Labelling of Refurbished Devices

Remanufactured by
GE Healthcare
GoldSeal
Waukesha, WI USA

Label P/N 5194808-2, Rev. X
# Medical Device Regulatory Framework (Recap)

**Figure 6. Common stages of government regulations**

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**Source:** WHO, *medical device regulations: global overview and guiding principles* (2003)
Conclusion

- Ensuring Safety of New / Refurbished Medical Device

*Manufacturers & Refurbishers*
- Mfg / Refurbish to (Original) Intended Use
- Subject to Audit of Quality Management System
- Use of International Standards to Ensure Safety & Performance
- Undertake Post market Surveillance and Vigilance activities (e.g. software / safety upgrades)

One yardstick for safety, quality & performance – “no double standard”
Thank You

(alfred.kwek@ge.com)