Selling and Certification Guidelines for TUV America:
(training copy)

Quality Systems

1)

- ISO 9000:

The model for quality assurance in design/ development, production, installation, and servicing for medical devices.

- ISO 9001:

The model for quality assurance in production, installation, and servicing for medical devices.

- ISO 9002:

The model for quality assurance in final inspection and testing for medical devices.

- ISO 13485:

Specifies requirements for a quality management system that can be used for the design/development, production, installation, and servicing of medical devices.

- ISO 13488:

Specifies requirements for a quality management system that can be used for the production, installation, and servicing of medical devices.

- EN46001:

European quality system standard, additive to EN ISO 9001.
(includes design process)

- EN46002

European quality system standard, additive to EN ISO 9002.
(does not include design process)

- CMDCAS:

In essence, it is the ISO 13485 with the stamp of the SCC (Standards Council of Canada) on it. A Notified Body such as TUV must be authorized by the SCC in order to issue a valid CMDCAS certification.

The CE Mark

MDD – Medical Device Directive
AIMDD – Active Implantable Medical Device Directive
IVDD – InVitro Diagnostic Device Directive

The CE Mark shows compliance to the European directives such as the MDD, AIMDD, or IVDDD, and can only be issued by an authorized Notified Body. These directives are product specific, and mandate that a quality system such as EN 46001 with ISO 9000 or ISO 13485 with ISO 9000 must be in place. There is one exception for the CE Mark: If a product is a Class I non-sterile product, a manufacturer may self-declare its conformity.

a) Within the **MDD** (Medical Device Directive), each product is further classified into the following categories:

Class I – non-sterile and non-measuring can be self- declared as conforming.
Class I – sterile
Class IIa
Class IIb
Class III – requires a design dossier

The manufacturer must satisfy the Essential Requirements outlined in Annex I

The manufacturer must appoint a European Representative in Europe, and establish a system of vigilance. This includes post production surveillance and incident reporting.

The manufacturer must establish a technical file/ design dossier for said product/product family, and provide such files to any competent authority that requests it. *Including self-declared Class I non-sterile products.

Certification Components for the CE Mark include:

1. Classification of Device
2. Conformity Route(s)
3. Compliance to Essential Requirements
4. Technical Documentation
5. EC Declaration of Conformity includes:
   Full Quality Assurance System
   Production Quality Assurance System
   Product Quality Assurance System
6. Vigilance System
7. Notified Body Evaluation
8. Determine European Representative / Entity
9. Register with CA (Competent Authority)

b) **AIMDD** (Active Implantable Medical Device Directive)

All devices must be certified by a Notified Body and follow the Certification Components listed above. There are two types of certification paths:

1. Annex II,
   Section 3, which includes a Quality Assurance System with Section 4, which involves a Design Dossier.

2. Annex III,
   Article 4 or Article 5, which involves an examination of the product and of the production, but does not need to include design or a full quality system.

c) **IVDDD** (In-Vitro Diagnostic Device Directive)

Devices are categorized based upon their degree of risk, which is evaluated primarily according to the potential for false results that may in turn threaten the health and safety of a patient.

The classifications are as follows:

Annex II, List A Devices	Highest degree of potential risk
Annex II, List B Devices	Highest degree of potential risk
Self- test Devices	Relatively low risk
“Other” Devices	Relatively low risk
Devices for Performance Evaluation/	

Clinical Trials Minimal risk, product under development

The In-Vitro Diagnostic Device Directive mandates that all devices fall into one of two categories, and one category requires certification by a Notified Body, and the other does not.

Devices not requiring certification from a Notified Body:

a) Class 1-1/ PE (Performance Evaluation)
Devices undergoing performance evaluation/ performance trials.

b) Class 1-2/ All "Other"
All "Other" IVD Devices not included in Class 2.

Devices requiring certification from a Notified Body:

a) Class 2-1/ Self- tests not included in Annex II
Self-test devices not included in Class 1 or Classes 2-2 through 2-4, and are considered low direct risk to patient.

b) Class 2-2/ Annex II self-tests
c) Class 2-3/ Annex II, List B
d) Class 2-4/ Annex II, List A

Certification components of the IVDD include:

1. EC Declaration of Conformity (DOC)
2. Design Exam Certificate
3. EC, DOC, Full (QA) Quality Assurance System
4. Design Dossier Certificate
5. EC Type Examination
6. EC Verification
7. EC DOC, Production QA
8. Batch Release Certificate, Production QA
9. Performance Evaluation Statement

Product Safety Testing

Regulatory mandates:

IEC/EN60601-1 (comprised of a series of tests)

There are quite a few product safety tests that are equivalent to the IEC/ EN 60601-1.
IEC = International Electrical Commission
EN= European Norm
ISO= International Standardization Organization
UL = Underwriter's Laboratories (United States)
CSA = Canadian Standards Association- the test is CSA 22.2 no. 601.1 (tests at 30 amps)
BSI/ BS = British Standards Institute
NF = French
DIN = German
VDE = German test house that also publishes standards

- The history of IEC 60601-1:

IEC 60601-1: 1988
IEC 60601-1: 1991, Amendment 1
IEC 60601-1: 1995, Amendment 2

UL 2601-1 = was the IEC standard with additional requirements for components, cables, etc. with more of a focus on fire protection – for U.S. market only.

*Europe focuses more on risk of electrical shock, and the U.S. focuses more on fire protection.

- The IEC/ EN 60601-1 standard

1. 60601-1-x:
Collateral standards – applies to all medical devices/ systems.
I.e. connecting a medical device to a non-medical device (a monitor to a computer) mandates that the whole system must comply with the standard, and whoever configures the system is then responsible for compliance.

2. 60601-1-2:
EMC
The new standard has a transition period until Nov.1, 2004. As of November 1, 2004, EN 60601-1-2:1993 will be obsolete. Application of EN 60601-1-2:1993 is still possible until October 30, 2004, but placing on the market after October 30, 2004 is not.

3. 60601-1-3:
Protection against ionizing radiation – limited to X-ray equipment.

4. 60601-1-4 Programmable medical devices
Must have software/ microprocessor within device.

- The 60601-2-x standard

Particular standards for specific devices
Goes from 60601-2-1 to 60601-2-50

- The 60601-3- x standard

Not released yet, but will deal more with the performance rather than the safety of the device.

- There are 10 Sections to the 60601-1-x standard

1. General Requirements
2. Environmental Conditions
3. Protection against electric shock
4. Protection against mechanical hazards
5. Protection against unwanted or hazardous radiation
6. Protection against hazards of ignition of flammable anesthetic mixtures
7. Protection against excessive temperatures and other safety hazards
8. Accuracy of operation and protection against of hazardous output
9. Abnormal operation and fault conditions
10. Constructional requirements

- The 10 Sections of the 60601-1-x standard in detail

1. General Requirements (Sub clauses 1-7)

Classification of the device is addressed in this section. Classification is done based on technology and the type of protection against potential electrical shock.

a) Class I – the plug has three prongs that ensure a short circuit as a safety mechanism, and the device has a metal enclosure.
b) Class II - the plug has two prongs, therefore it will not short-circuit if overloaded, but the enclosure is made of a plastic, which is not a conductor.
c) Internally powered

Second classification is based on the degree of protection from electric shock

a. B = lowest degree of protection
b. BF = medium degree of protection
c. CF = the highest degree of protection. The device is 'floating' – it has no connection to the ground.

The third classification is based on the protection against the ingress of water. (from IEC 60527) Ipxx.
1st x refers to the = Protection against presence of physical material
2nd x refers to the = Protection against water, and the range is 0 – 8.

2. Environmental Conditions (Sub clauses 8 – 12)

Addresses atmospheric conditions such as:
Temperature (device must perform in the range between 10C and 40C/ 50F – 100F)
Air pressure (700 – 1060 Hector Pascals)
Humidity (30 – 75%)

3. Protection against electric shock (Sub clauses 13 – 20)

Sub Clause 18 – **electrical impedance**

Sub Clause 19 - leakage current
Addresses the current flowing from the device to different elements –
Earth leakage current
Enclosure leakage current
Patient leakage current
Patient auxiliary current – the current actually needed for performance, but should be as minimal as possible – i.e. the current between electrodes.

Sub Clause 20 – tests the insulation barrier
The barriers are classified by the degree of insulation they provide. "Dangerous" refers to the potential harm to body parts.

SIP/SOP – Signal input part, signal output part
I.e. parts that connect to other components – i.e. a patient monitor that connects to the main nurses station. That whole system must be compliant.

HI POT – High potential testing
Tested at 4000 V or less, depending on the type of barrier and amount of voltage

4. Protection against mechanical hazards (Sub clauses 21 – 28)

Addresses basic set-up and vibration noise

5. Protection against unwanted or hazardous radiation (Sub clauses 29 – 36)

Alpha
Beta
Gamma
X-Ray
Acoustical energy – includes ultrasound
EMC
Ultraviolet
Neutron
Microwave
Light – includes lasers

Infrared

6. **Protection against hazards of ignition of flammable anesthetic mixtures (37 – 41)**

Most devices do not have any protection. They are classified into three different categories:
No protection
AP – The least amount of protection
APG – The highest amount of protection

7. **Protection against excessive temperatures and other safety hazards (42 – 49)**

Temperatures
Fire protection
Humidity/ water
Biocompatibility – i.e. 48:ISO 10993 – catheters, heart valves, etc.

Sub Clause 49 – Interruption of power supply

8. **Accuracy of operation and protection against of hazardous output (50 – 51)**

9. **Abnormal operation and fault conditions (Sub clauses 52 –53)**

10. **Constructional requirements (Sub clauses 54 – 59)**

Such as the types of wire, circuitry used, transformers, enclosure, etc.

- The testing process

Step 1: perform Sub Clause 19 – measure leakage current

Step 2: perform Sub Clause 20 – HI POT test

Step 3: perform pre-conditioning
The device is placed in a chamber with a controlled environment of a temperature of 25C and 93% humidity +/- 3%.
The device remains in the chamber for 48 hours if the Ipx is 0 (refer back to the ingress of water) and 7 days if the Ipx is 1 or greater.

Step 4: measure device against Sub Clauses 19 and 20 again for consistency

*Depending on the manufacturer and the level of effective communication, the tests can take anywhere from a week to three to six months.

- Additional definitions

Air clearance: The distance between two or more electrical points measured in air space.

Creepage distance: The distance between two or more electrical points must be established in order to prevent a change in voltage level. This is measured on surface material because the surface may have dust or other particles on it that will effect the effectiveness of insulation.

Live parts: The state of a part that contains a current whose voltage can harm a person.

Applied parts: A physical component of the device that a patient intentionally comes in contact with. I.e. an electrode.

R= Resistance
I=Current
U= Voltage

U=R x I (Voltage = Current x Resistance)
Therefore, the higher the voltage, the higher the current given that the resistance stays the same. The higher the resistance, the lower the current, so manufacturers strive for close to zero resistance.

Single Fault Condition:
With all other devices, once a fault occurs then the device shuts down. With medical devices, this cannot occur. Medical devices must be safe after the first fault appears.

Description of the 510K Review/ PMN (Pre-market notification) for the FDA:

Section 510K of the Food, Drug, and Cosmetic Act requires all medical device manufacturers to register with the FDA at least 90 days before they intend to market a medical device. The purpose is to allow the FDA to determine whether the device is equivalent to a device already on the market and if it can be categorized into either Class I, Class II, or Class III categories.

Additionally, a 510K Review/ PMN must be submitted if the medical device manufacturer wants to change the device significantly (i.e. design, material, chemical composition, energy source, manufacturing process, intended use, etc.)

CBCM/ CB Scheme:

A voluntary system created by the NCB (National Certification Body), it mandates that all CBs (Certified Bodies) will perform safety tests to IEC standards, and all other CB test houses will recognize and accept such results from other test houses. A manufacturer can then apply for national approvals from different countries using these results, thus saving a great deal of time and money.

CB certification = $2000
CB report = $1450
Total = $3450

This is for the EN 60601-1 product safety tests

There is an additional $800 charge for the EN 60601-1-2 tests