Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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The Essential Principles

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Their origin…….

- EU Medical Device Directive 93/42/EEC – Annex I
  - Essential Requirements
- GHTF SG1 - commences work on premarket framework – 1994
- Canada - Medical Device Regulations 1998 - Part 1
  - Safety and Effectiveness Requirements
- Japan – Medical Device regulations – 2000
  - Essential Principles
- Australia – Therapeutic Goods (MD) Regulations 2002 – Schedule 1
  - Essential Principles

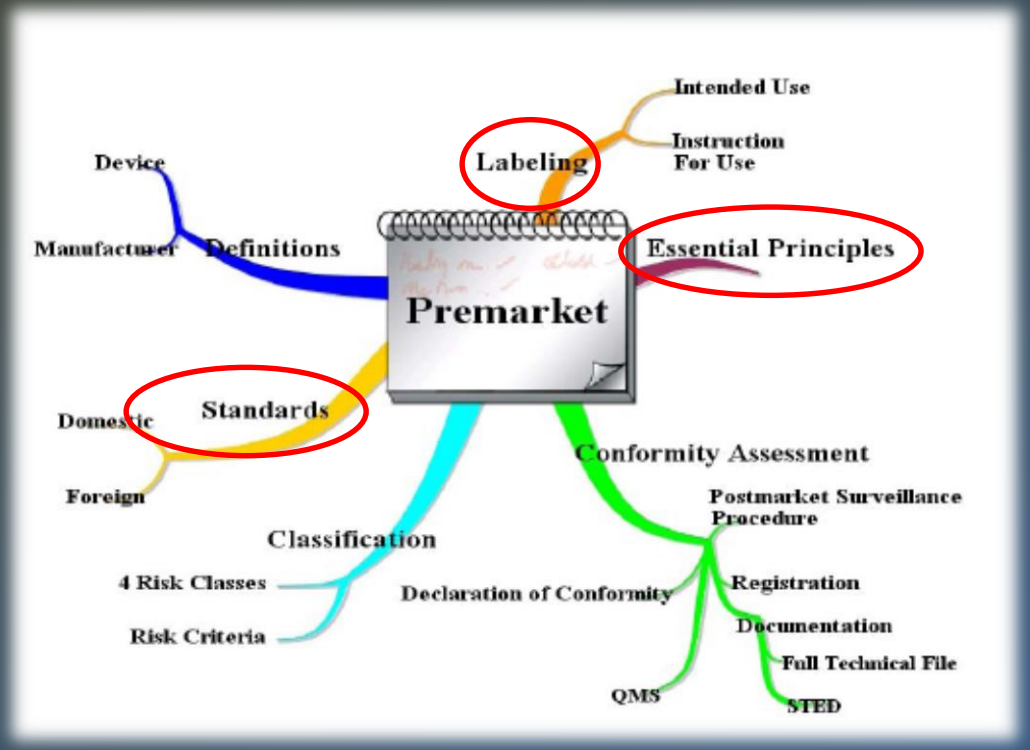
Their origin…….

- GHTF – SG1/N41/R9:2005
  - Essential Principles of Safety and Performance of Medical Devices
- AHWP – AHWP/WG1a/F002:2013
  - Essential Principles of Safety and Performance of IVD Medical Devices
- ASEAN Medical Device Directive:2015
  - Essential Principles of Safety and Performance of IVD Medical Devices

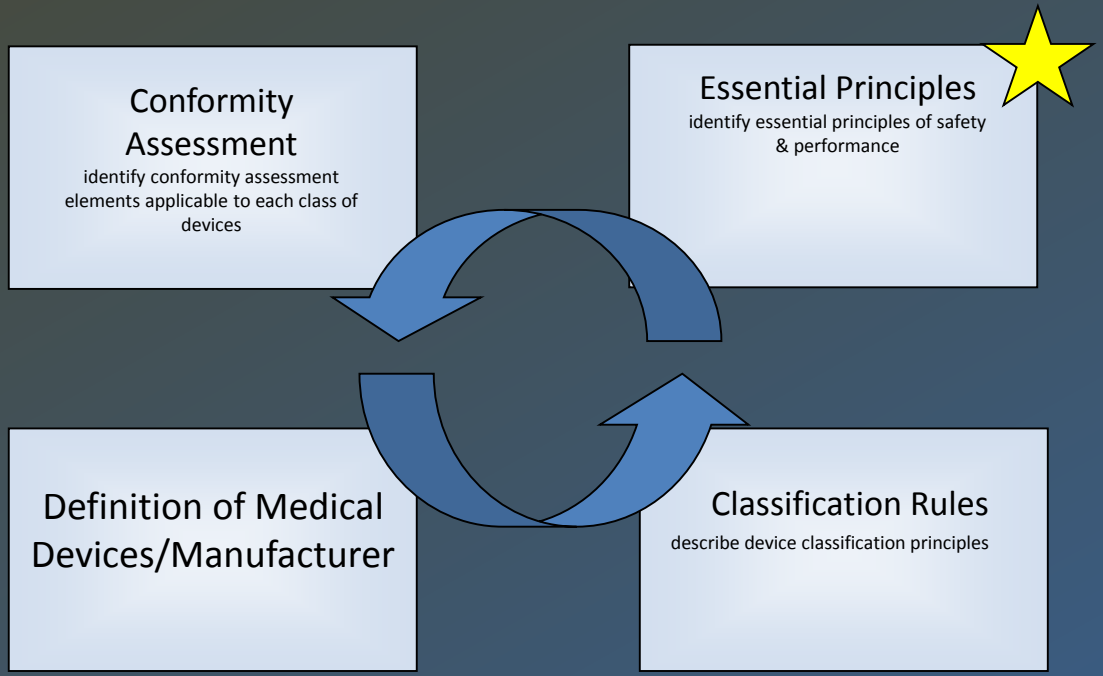
And now .....

- India
  - Medical Device Rules 2017
    - Chapter 2, Rule 6
    - Guidance (currently in DRAFT)

Pre-Market Requirements



Pre-Market Requirements



Importance of Essential Principles

- "Consistent identification, selection and application of safety and performance principles to a medical device offers significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities since it allows its manufacturer to design, manufacture and demonstrate the device is suitable for its intended use. …"

- "… Moreover, eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments."

- GHTF/SG1/N77:2012 - Essential Principles of Safety and Performance of Medical Devices

Essential Principles

— Relate to safety and performance,

— Are applicable to all devices, independent of the risk class, and

— The principles are not objective pass/fail criteria

Essential Principles

- Six general principles
  - Applicable to all medical devices
- Ten relating to design and construction
  - Some only applicable, depending on the technology used
- One for information accompanying a device
  - Applicable to all devices
  - Labelling and instructions for use.
- One relating to the form of clinical evidence
  - Applicable to all devices
  - Refers to the method for generating clinical evidence
    - The Declaration of Helsinki.

Essential Principles

- Essential Principles lay down the necessary elements for protecting the public interest e.g. health, safety and environmental issues i.e. all that is necessary to achieve objective of regulatory AMDD. (Article 3)
- They define the results to be attained or the hazards to be dealt with, they do not specify the technical solutions to be adopted
- They are not based on technical requirements and are not affected by technological progress or innovation. Consequently, they are not subject to regular revision.
- They are mandatory when applicable. Rationales for non-compliance are not an option

Essential Principles

- From a technical perspective they are the most important aspect of any regulatory framework (AMDD)
- Compliance to EP's is based on principle of "presumption of conformity"
  - Comply with relevant standards → comply with EP's
  - Ref to the hierarchy of standards
- EP's 1-6 are general requirements, focus is on safety and performance taking risk and risk benefits into consideration
- EP #2 includes "state of the art" requirement
  - EP's don't change but "state of the art" does
  - Products/files should be maintained in line with development of new requirements/standards etc.

Purpose

- "To describe six **general requirements** of safety and performance that apply to all medical devices.

- "… These are grouped as:
  - Safety principles
  - Risk to patient, user or environment and risk/benefit
  - Performance
  - Transport and storage
  - Labelling and IFU
  - Clinical Evidence and/or performance

- The manufacturer selects which of the design and manufacturing requirements are relevant to a particular medical device, documenting the reasons for excluding the others.

- The Regulatory Authority and/or Conformity Assessment Body may verify this decision during the conformity assessment process." (or audit)

Purpose

- To provide a comprehensive list of **design and manufacturing requirements** of safety and performance, some of which are relevant to each medical device. …"

- "… These are grouped as:
  - Chemical, physical and biological properties
  - Infection and microbial contamination
  - Manufacturing and environmental properties
  - Devices with a diagnostic or measuring function
  - Protection against radiation
  - Requirements for medical devices connected to or equipped with an energy source
  - Protection against mechanical risks …

“State of the art”

“The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the **generally acknowledged state of the art**.”

- How do we determine the current “state of the art”?
- How does the state of the art change over time?
- How does post-market surveillance help establish the state of the art?

“State of the art”

- ISO 14971, Annex D (informative)
  - *“State of the art” is used here to mean what is currently and generally accepted as good practice. Various methods can be used to determine "state of the art" for a particular medical device. Examples are:*
  - *– standards used for the same or similar devices;*
  - *– best practices as used in other devices of the same or similar type;*
  - *– results of accepted scientific research.*
  - *State of the art does not necessarily mean the most technologically advanced solution.*

Demonstrating conformity

- The tools –
  - Selected standards (ISO, IEC, EN, etc)
    - EU – ‘Harmonised’ standards
    - ASEAN – ‘Recognised’ standards……
  - Manufacturer test protocols
    - In the absence of a relevant standard
  - Clinical Evidence

“State of the art”

- Using fundamental principles is the easiest way for manufacturer to confirm device is ***“state of the art”*** as required

- *“state of the art”* not defined by, but companies may internally define it as:

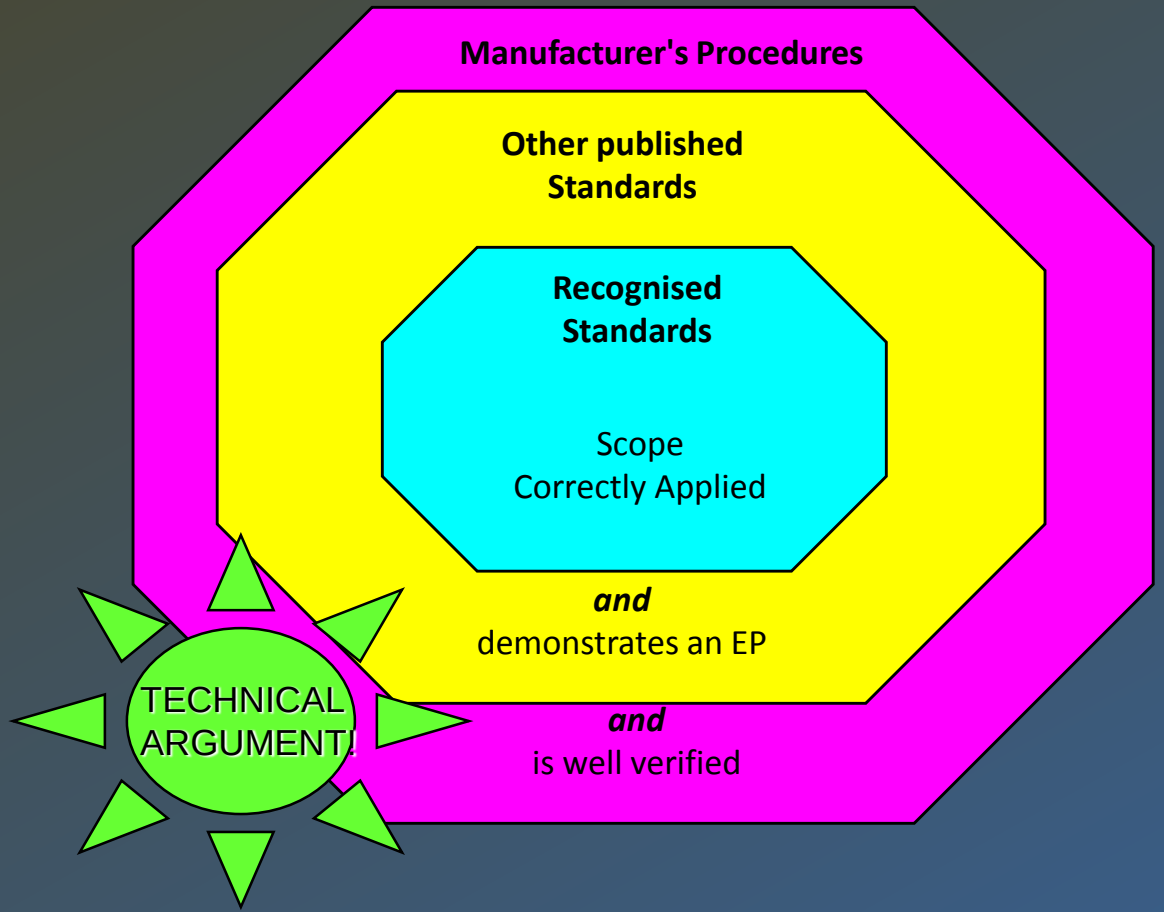
Term used to signify that the device design, construction and technical documentation is considered to be up-to-date. In practical terms, for a device described as "state of the art," the following aspects should be considered:

- *current harmonized standards have been used to demonstrate conformity with the Essential Principles*
- *the device's technical documentation (Design Dossier or Technical File) is an accurate reflection of the device and manufacturing/quality system processes*
- *the device risk management and clinical documentation is up to date, based on device / relevant general experience*

Note: *"state of the art" does not necessarily mean the most technologically advanced solution; the device technology and manufacturing processes applied should be considered relatively modern and generally should not encompass use of obsolete technology.”*

Demonstrating conformity

- **Presumption of Conformity**
  - Compliance with Harmonized Standards presumes conformity to Essential Principles
- **recognised Standards**
  - A recognized standard gives technical expression to the Essential Principles
  - Regularly revised to maintain ‘state of the art’
  - However, compliance **not** mandatory
    - in order not to restrict technological innovation, more flexible regulatory solutions.
- However……. Compliance to a reconised standard is by far the easiest route to demonstrating compliance to EP’s


Manufacturer's Procedures
Other published Standards
Recognised Standards
Scope
Correctly Applied
and
demonstrates an EP
and
is well verified
TECHNICAL ARGUMENT!

In Summary

- Essential Principles form the foundation of harmonized global regulatory model

- They
  - are comprehensive in scope
  - cover safety and performance
  - define design requirements
  - do not define methods of achieving, demonstrating, or documenting conformity
  - are most often addressed by using international standards

In summary

- The manufacturer must apply all general principles and all relevant specific principles
- They are flexible to accommodate advances in the state of the art and new medical devices / technologies / intended uses
- They recognize risks and benefits associated with medical devices
- They are founded on risk management principles
- They are intimately linked to a manufacturer's quality system for design, manufacture, and risk management

But……

- They have their origins back in the early 90's
- Technologies and the practice of medicine has moved on…….

Essential Principles

- Essential Principles lay down the necessary elements for protecting the public interest e.g. health, safety and environmental issues i.e. all that is necessary to achieve objective of regulatory AMDD. (Article 3)
- They define the results to be attained or the hazards to be dealt with, they do not specify the technical solutions to be adopted
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- The EP's originated from the EU ER's……93/42/EEC and 9/385/EEC
  - 13 EP's in MDD
  - 16 EP's in AIMD

- Now –EU Medical Device Regulations 2017
  - 23 General Safety and Performance Requirements

New considerations from Annex I

- medicinal substances (and substances absorbed or locally dispersed);
- devices incorporating materials of biological origin
- substances of concern
  - Nano particles, latex, phthalates……..
- labelling requirements
- cybersecurity

- Other key areas of impact in the MDR outside Annex I include:

  - clinical data and evaluation requirements
  - reclassification of some device types
  - post-market requirements

Perhaps now is the time to revisit the EP's ……

- But who ……..
  - IMDRF
  - AHWP
  - Individual regulators

Questions, comments, thoughts ……

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