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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Classification Rules for Medical Devices

Greg LeBlanc

Outline

- What is “classification” of medical devices?
- Why do it?
- What methods are there?
- Review of the GHTF Classification Guidance Document

What is “Classification”?

- In this context, a process for assigning medical devices to a group or “level” for regulatory purposes
- For what we are talking about here, these classifications may sometimes be referred to as “risk class” or equivalent, as it is generally done on the basis of the perceived risk/potential hazards associated with the device

What is “Classification”?

- Concept applies to both general medical devices, and *in vitro* diagnostics (IVDs)

Why Classify?

- Why bother? Does it matter?
  - Depending on regulatory system, it can be an integral component of the model, or not relevant at all!
  - Plays an important role in most systems, though
- Allows for a stratification of approach depending on the classification

Nomenclature

- Generally numeric or alphabetic, though numeric is most common, e.g.:
  - Canada: Class 1, 2, 3, 4
  - U.S.: Class 1, 2, 3
  - E.U.: Class 1, 2a, 2b, 3
  - GHTF: Class A, B, C, D

Methods of Classification

- Can be grouped into two general methods:

List-Based	Rules-Based

List-Based Classification Methods

- Method by which devices are classified according to a list published by the regulator:
  - Assigned directly to a class
  - E.g. “Artificial heart valves are Class 3 devices”

Rules-Based Classification Methods

- Method by which devices are classified according to “if/then” rules published by the regulator – if a device meets an outlined rule, then it is classified accordingly
  - E.g. “all devices that contain human- or animal-derived tissue products are Class 4”

Which Method is Best?

- Each method has “pros” and “cons”:

List-Based Approach

Positives	Drawbacks
• More definitive for users • Can choose what does and doesn't appear on the list • Allows adaptation at a granular level over time	• Potential for over/under regulation within product family/name • Requires regular updates • May not capture everything • Difficult to deal with innovation

Rule-Based Approach

Positives	Drawbacks
• Comprehensive, can cover all products (current and new) • Once set, generally requires maintenance on infrequent basis	• Lack of flexibility over time for established products • Difficult to deal with “exceptions” when warranted • Requires interpretation by users • Can be complex

Which Method is Best?

- Generally, the consensus seems to be that the rules-based approach is best for the long term, but not everyone necessarily agrees!
  - List-based approach may serve a short-term or transitional purpose and/or be hybridized into the rules
- This is the approach chosen by the GHTF for its global model and elucidated as part of the AHWP model in the Playbook

The AHWP Model

- The principles and rules for classification within the AHWP framework are found in two documents:
  - For general medical devices – the GHTF SG1/N77:2012 document – *"Principles of Medical Device Classification"*
  - For in vitro diagnostics – the AHWP WG2/F001:2016 document – *"Principles of In Vitro Diagnostic (IVD) Medical Devices Classification"*

General Medical Devices

- The GHTF SG1/N77 document was an update of an earlier document (N15) published in 2006
- I'll provide a brief outline of the document and then we can run through the rules
- (GMD = general medical devices)

GHTF Principles of GMD Classification

- Starts with introductory sections on rationale, purpose and scope
- Next is definitions
  - These are *very* important to support the rules; e.g. “active medical device”, “central circulatory system”, “duration of use”, “invasive devices”

GHTF Principles of GMD Classification

- Next section is “General Principles”
  - Regulatory oversight varies by class
  - Some of the factors that go into determining the classification of a device
- Then is an overview of the system
  - Classes A, B, C, D with D being the most hazardous
  - If more than one rule applies, use the highest
  - Importance of “intended use”

GHTF Principles of GMD Classification

- Section 7 outlines the rules themselves:

GHTF Principles of GMD Classification

Rule 1:

- All non-invasive devices which come into contact with injured skin:
  - Class A if a mechanical barrier, for compression, or absorption of exudates only
  - Class B if used with wounds which have breached the dermis, unless they can only heal by secondary intent in which case they are Class C (e.g. of Class C – dressing for chronic ulcerated wounds)

GHTF Principles of GMD Classification

Rule 2(i):

- All non-invasive devices intended for channeling or storing liquids or gases:
  - Class A if for the purpose of eventual infusion, administration or introduction into the body, but…
  - Class B if they may be connected to an active medical device that is itself in Class B or higher

GHTF Principles of GMD Classification

Rule 2(ii):

- All non-invasive devices intended for channeling blood, storing or channeling other body liquids, or storing organs, parts of organs, or body tissues:
  - Class B if for the purpose of eventual infusion, administration or introduction into the body, but…
  - Class C if they are blood bags

GHTF Principles of GMD Classification

Rule 3:

- All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids, or other liquids intended for infusion into the body:
  - Class C, but…
  - Class B if the treatment consists of filtration, centrifugation, or exchanges of gas or heat

GHTF Principles of GMD Classification

Rule 4:

- All other non-invasive devices:
  - Class A

GHTF Principles of GMD Classification

Rule 5:

- All non-surgically invasive devices (i.e. via body orifice):
  - not intended for connection to an active device or intended only for connection to Class A active device:
    - Class A if for transient use
    - Class B if for short-term use, unless in oral cavity as far as the pharynx, ear canal as far as ear drum or nasal cavity, then Class A
    - Class C if for long-term use, unless oral cavity, ear canal or nasal cavity as above and not absorbed, then Class B
  - Intended for connection to an active device of Class B or higher, then Class B

GHTF Principles of GMD Classification

Rule 6:

- All surgically invasive devices for transient use are Class B unless:
  - Reusable surgical instruments, then Class A
  - Intended to supply ionizing radiation, then Class C
  - Intended to have a biological effect or be absorbed, then Class C
  - Intended to administer medical products if done in a manner that is potentially hazardous, then Class C
  - Intended specifically for direct contact with the CNS, then Class D
  - Intended to diagnose, monitor or correct a defect of heart or central circulatory system through direct contact, then Class D

GHTF Principles of GMD Classification

Rule 7:

- All surgically invasive devices for short-term use are Class B unless:
  - Intended to administer medical products, then Class C
  - Intended to undergo chemical change in the body (except in teeth), then Class C
  - Intended to supply ionizing radiation, then Class C
  - Intended to have a biological effect or be absorbed, then Class D
  - Intended specifically for direct contact with the CNS, then Class D
  - Intended to diagnose, monitor or correct a defect of heart or central circulatory system through direct contact, then Class D

GHTF Principles of GMD Classification

Rule 8:

- All implantable devices and surgically invasive devices for long-term use are Class C unless:
  - Intended to be placed in teeth or on prepared tooth structure, then Class B
  - Intended for direct contact with heart, central circulatory system, or the CNS, then Class D
  - Intended to be life supporting or life sustaining, then Class D
  - Intended to be active implantables, then Class D
  - Intended to have biological effect or be absorbed, then Class D
  - Intended to administer a medicinal product, then Class D
  - Intended to undergo chemical change (except in teeth), then Class D
  - Are breast implants, then Class D

GHTF Principles of GMD Classification

Rule 9(i):

- All active therapeutic devices intended to administer or exchange energy are Class B unless:
  - The administration or exchange of energy is potentially hazardous, then Class C

GHTF Principles of GMD Classification

Rule 9(ii):

- All active devices intended to control or monitor the performance of Class C active therapeutic devices, or intended to directly influence their performance, are Class C.

GHTF Principles of GMD Classification

Rule 10(i):

- All active devices intended for diagnosis are:
  - Class B if intended to supply energy which will be absorbed
    - Unless solely to illuminate with visible or near infrared light, then Class A
  - Class B if intended to image in vivo distribution of radiopharmaceuticals
  - Class B if intended to allow direct diagnosis or monitoring of vital physiological processes
    - Unless the nature of variations is such that it could result in immediate danger to the patient, or used in clinical situations where the patient is in immediate danger, then Class C

GHTF Principles of GMD Classification

Rule 10(ii):

- All active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are Class C

GHTF Principles of GMD Classification

Rule 11:

- All active devices intended to administer and/or remove medicinal products, body liquids or other substances are Class B,
  - Unless this is done in a potentially hazardous manner, then Class C

GHTF Principles of GMD Classification

Rule 12:

- All other active devices are Class A

GHTF Principles of GMD Classification

Rule 13:

- All devices incorporating, as an integral part, a medicinal product that is liable to act on the human body, is Class D

GHTF Principles of GMD Classification

Rule 14:

- All devices incorporating animal or human cells/tissues/derivatives thereof are Class D
  - Unless non-viable animal tissues that come only in contact with intact skin, then Class A

GHTF Principles of GMD Classification

Rule 15:

- All devices intended for use in sterilizing or disinfecting medical devices are Class B, unless:
  - Disinfectant solutions or washer-disinfectors intended specifically for invasive medical devices as the end point of processing, then Class C
  - Intended to clean by means of physical action only, then Class A

GHTF Principles of GMD Classification

Rule 16:

- All devices intended for use in disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are Class C

GHTF Principles of GMD Classification

Rule 17:

- All devices intended for contraception or the prevention of the transmission of sexually transmitted diseases are Class C
  - Unless implantable or long-term invasive, then Class D

GHTF Principles of GMD Classification

- The document also includes an appendix made up of a series of decision trees to help guide the user through the classification rules

In Vitro Diagnostics

- The AHWP WG2/F001 document was an adaptation of the GHTF SG1/N045 document published in 2008 and closely parallels that document

AHWP Principles of IVD Classification

- Starts with introductory sections on rationale, purpose, scope and references
- Next is definitions
  - Like with GMDs these are critical to support the rules, e.g. companion diagnostic, near patient testing

AHWP Principles of IVD Classification

- Next sections are “General Principles” and “Recommendations and Factors Influencing Classification”
  - Regulatory oversight varies by class
  - Some of the factors that go into determining the classification of a device
  - How system should be organized
  - Classes A, B, C, D with D being the most hazardous
  - If more than one rule applies, use the highest
  - Importance of “intended use”
  - Considerations for accessories, calibrators and control materials

AHWP Principles of IVD Classification

- Section 7 provides general outline of the classification system and some basic examples of IVDs in each risk class, generally divided according to:
  - Class A: Low Individual Risk and Low Public Health Risk
  - Class B: Moderate Individual Risk and/or Low Public Health Risk
  - Class C: High Individual Risk and/or Moderate Public Health Risk
  - Class D: High Individual Risk and High Public Health Risk

AHWP Principles of IVD Classification

- Section 8 provides a practical mechanism for determining the risk class of an IVD, describing how to use the rules
- Section 9 provides the rules themselves:

AHWP Principles of IVD Classification

Rule 1:

- The following are Class D:
  - IVDs intended to be used to detect the presence of, or exposure to, a transmissible agent in blood or derivatives, cells, tissues or organs for transfusion or transplantation
  - IVDs intended to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with high risk of propagation

AHWP Principles of IVD Classification

Rule 2:

- IVDs intended for blood grouping or tissue typing to ensure immunological compatibility of blood, blood components, cells, tissues or organs intended for transfusion or transplantation are Class C, except
  - Specified ABO, Rh, Kell, Kidd and Duffy system determinations which are Class D

AHWP Principles of IVD Classification

Rule 3:

- The following IVD is intended for one of the following purposes, it is Class C:
  - Detecting presence of or exposure to a sexually transmitted agent
  - Detecting presence in CSF or blood of an infectious agent with risk of limited propagation
  - Detecting present of an infectious agent where there is a significant risk of death or severe disability in case of erroneous result

AHWP Principles of IVD Classification

Rule 3 (continued):

- The following IVD is intended for one of the following purposes, it is Class C:
  - Prenatal screening to determine immune status towards transmissible agents
  - Determining infective disease or immune status where there is a risk that erroneous result will lead to life-threatening patient management decisions
  - Companion diagnostics for primary therapy decisions

AHWP Principles of IVD Classification

Rule 3 (continued):

- The following IVD is intended for one of the following purposes, it is Class C:
  - Disease staging where an erroneous result would lead to life-threatening patient management decisions
  - Screening/diagnosis/staging of cancer
  - Genetic testing

AHWP Principles of IVD Classification

Rule 3 (continued):

- The following IVD is intended for one of the following purposes, it is Class C:
  - Monitoring levels of medicines, substances or biological components where there is a risk an erroneous result would lead to life-threatening patient management decisions
  - Management of patients suffering from a life-threatening infectious disease
  - Screening for congenital disorders

AHWP Principles of IVD Classification

Rule 4:

- IVDs intended for self-testing are Class C, unless:
  - The result is not determining a medically critical status, or is preliminary and requires follow-up with a laboratory test, then Class B
- IVDs for near-patient testing are:
  - Class C if for blood gases or blood glucose,
  - Otherwise classified per the other applicable Rule(s).

AHWP Principles of IVD Classification

Rule 5:

- The following IVDs are classified in Class A:
  - Reagents or other articles intended by the manufacturer for IVD procedures related to a specific examination
  - Instruments specifically for use in IVD procedures
  - Specimen receptacles

AHWP Principles of IVD Classification

Rule 6:

- IVDs not covered in Rules 1 through 5 are Class B

AHWP Principles of IVD Classification

Rule 7:

- IVDs that are controls without a quantitative or qualitative assigned value are Class B

Document then ends with an Annex describing common test purposes for IVDs.

Quiz Time

Let’s work through some examples!

Quiz Time

Question:

What is the classification of a drug eluting metal vascular stent intended for use in the treatment of vascular strictures of the femoral artery? The drug “coating” is intended to help prevent restenosis.

Quiz Time

Answer:

Class D.

Other rules do apply to this type of technology (long-term implantable, etc.) but Rule 13 says all devices incorporating a medicinal substance liable to act on the body are Class D.

Quiz Time

Question:

What is the classification of a *bare metal* vascular stent intended for use in the treatment of vascular strictures of the femoral artery?

Quiz Time

Answer:

Class C.

Rule 8 says all implantable devices are Class C. One of the special cases under the Rule is for devices intended to be in contact with the central circulatory system, but the femoral artery does not fall within the definition in the document.

Quiz Time

Question:

What is the classification of a wire guide intended for use as part of a coronary angioplasty procedure? The wire guide is sold as a separate medical device on its own (not jointly packaged/labeled).

Quiz Time

Answer:

Class B.

We didn’t specify a duration of use, Rule 6 applies to surgically invasive devices for transient use and Rule 7 applies to short-term use (generally would consider Rule 7 to apply). Either way, Class B applies as the default condition under either rule unless an exception within the rule applies. Both rules indicate that devices that are intended to “diagnose, monitor or correct a defect of the heart or central cardiovascular system” are Class D, but that does not apply to the wire guide itself.

Quiz Time

Question:

What is the classification of a blood glucose self-testing device?

Quiz Time

Answer:

Class C.

Rule 4, governing IVDs for self-testing and near-patient testing applies in this case. The rule specifies that IVDs for self-testing are Class C, unless not determining a medically critical status.

Questions?

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THANK YOU!

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