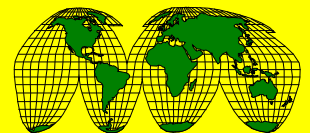


GHTF

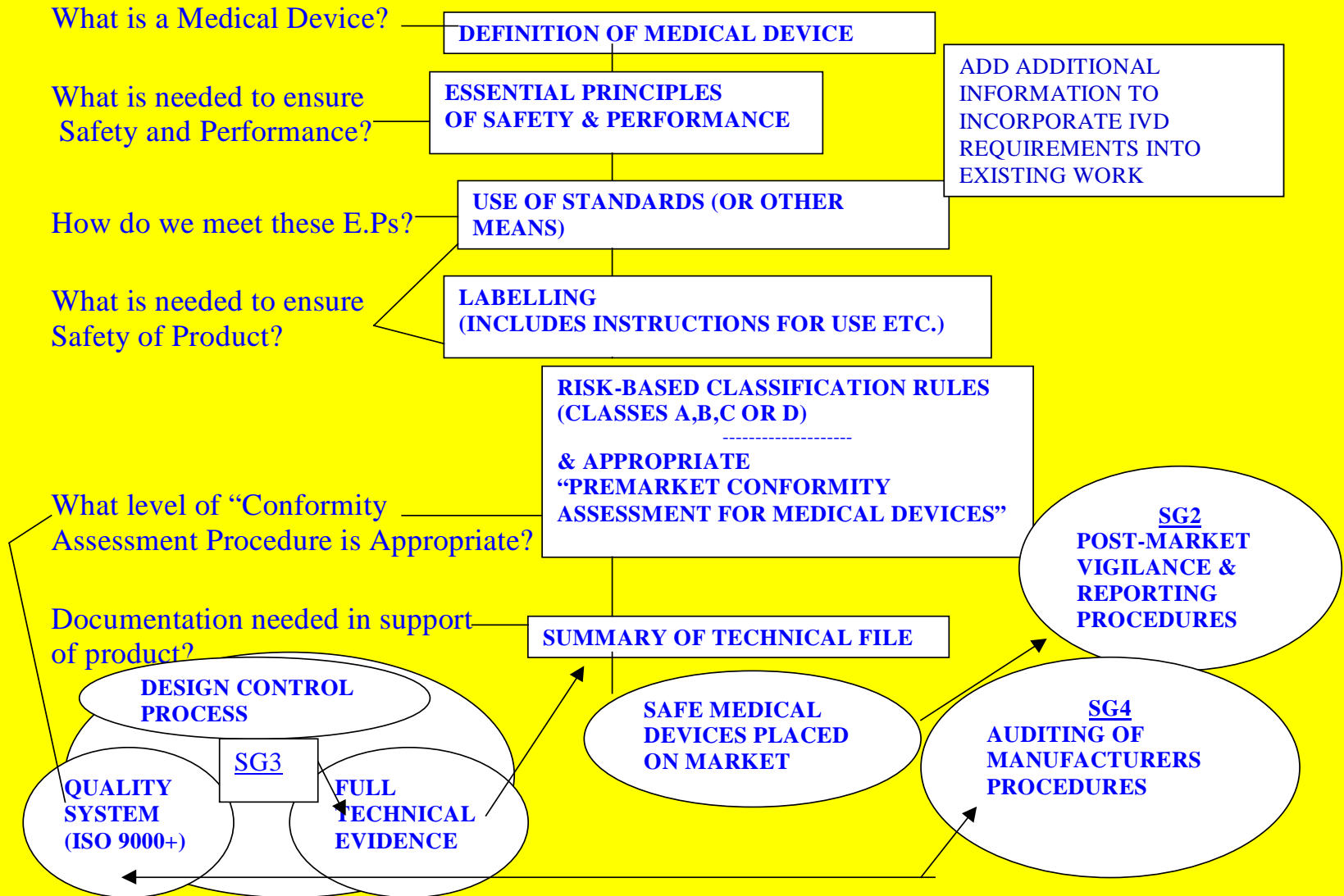
REPORT ON SG1

BY

M.F.FREEMAN



SCOPE OF GHTE-SG1 PREMARKET TECHNICAL REQUIREMENTS



				COMPLETION
<i>Medical Devices Classification</i>	SG1/N015	Proposed Document awaiting posting on GHTF web site	1	2002 / Q3
<i>Premarket Conformity Assessment for Medical Devices</i>	SG1/N040	Seeking comment on working draft	1	2002 / Q4
Pilot testing of <i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance(STED)</i>	SG1/N011	Pilot starting 2002 Q1 in some regions and finishing 2002 Q4	1	2003 / Q1
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance(STED)</i>	SG1/N011	Further work awaits results of pilot after 2002 Q4	2	2003 / Q2
<i>Information Document Concerning the Definition of the Term “Medical Device”</i>	SG1/N029	Proposed Document awaiting posting on GHTF web site	2	2002 / Q2
<i>Revision of Labelling for Medical Devices</i>	SG1/N043	Proposed Document awaiting posting on GHTF web site	3	2002 / Q3
<i>Revision of Essential Principles for Safety and Performance of Medical Devices</i>	SG1/N041	In work to incorporate IVDDs	3	2002 / Q3
<i>Revision of Role of Standards in the Assessment of Medical Devices</i>	SG1/N044	Secretary preparing first draft to incorporate IVDDs	3	2002 / Q3
<i>Classification of In Vitro Diagnostic Devices</i>	SG1/N045	Sub-group preparing first draft	4	2003 / Q1
<i>Premarket Conformity Assessment for In Vitro Diagnostic Devices</i>	SG1/N046	Sub-group preparing first draft	4	2003 / Q1

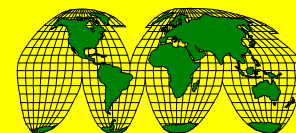


PROPOSED DOCUMENT
Global Harmonization Task Force

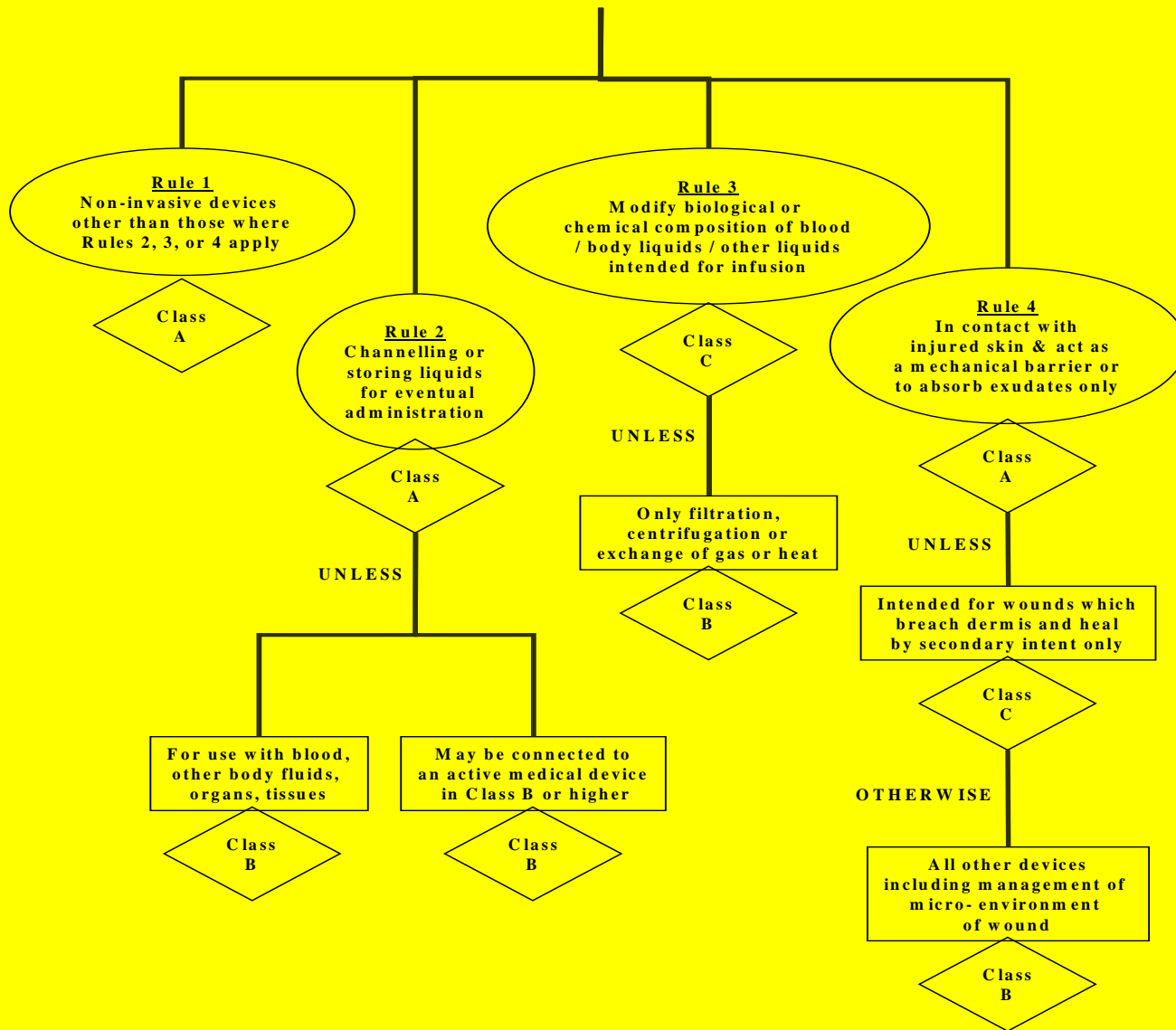
Title: Medical Devices Classification

Authoring Group: Study Group 1 of the Global Harmonization Task Force

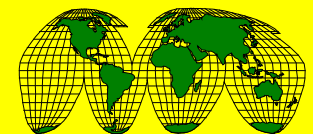
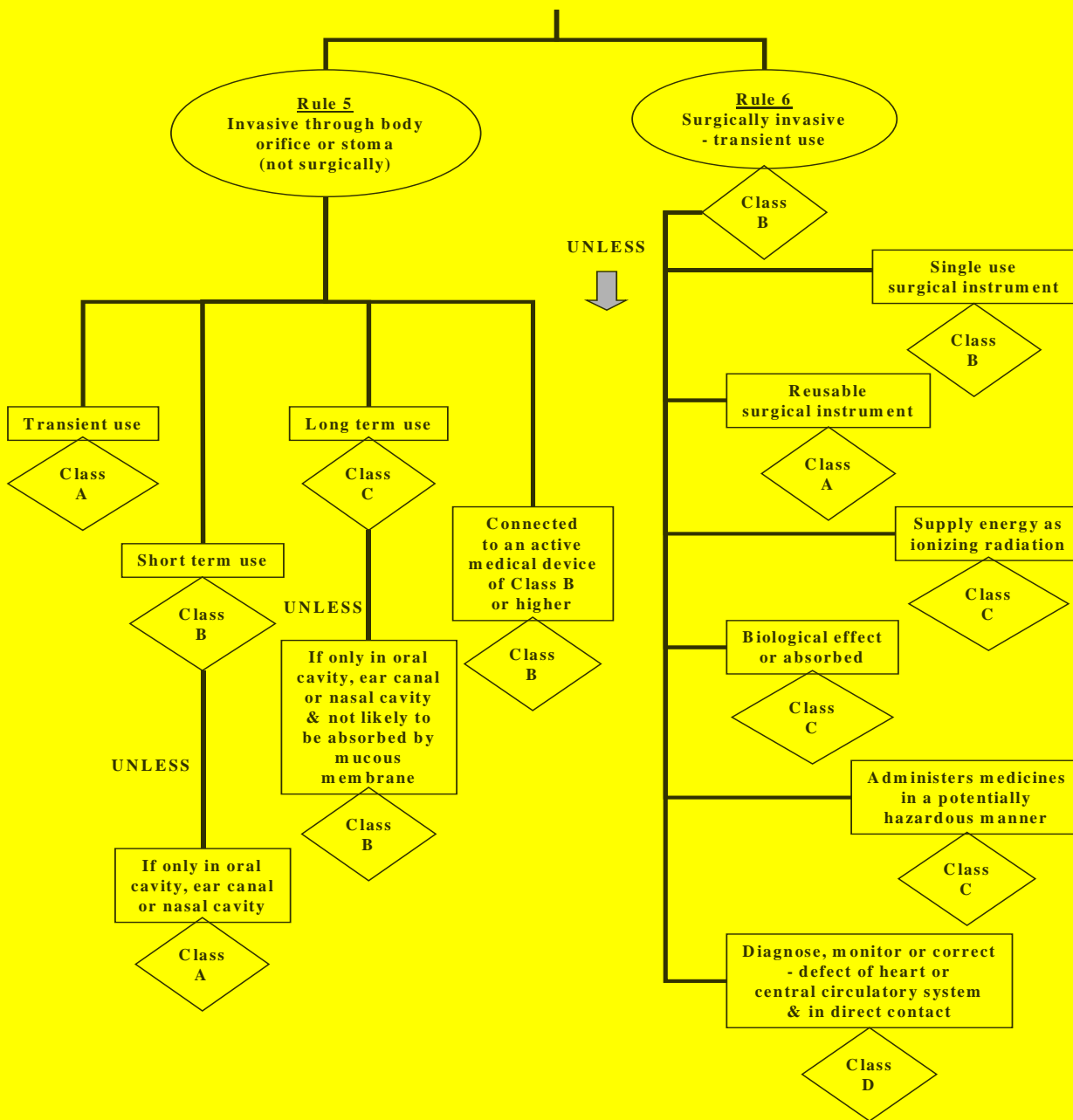
Date: November 21, 2001
08/05/02

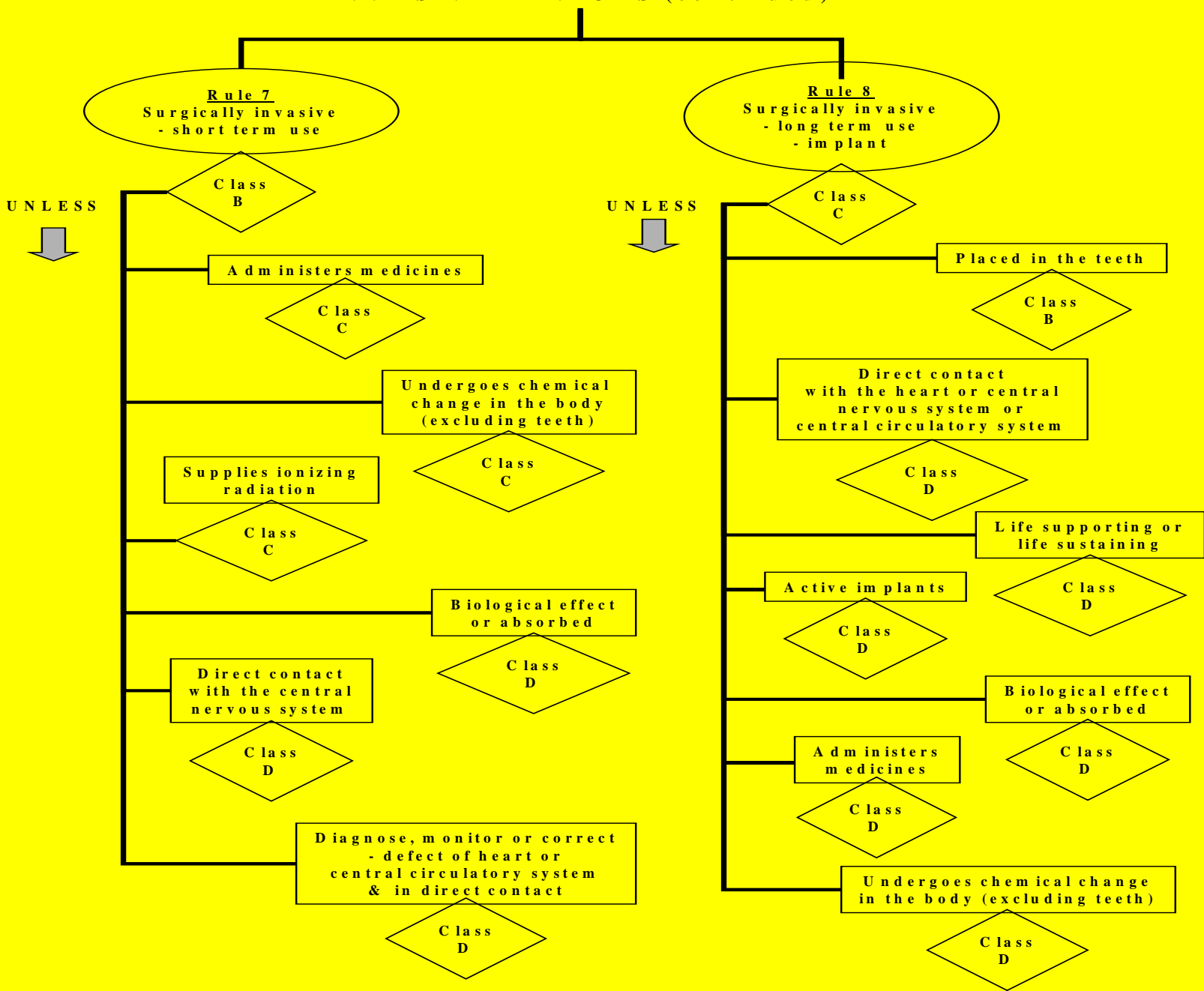


NON-INVASIVE DEVICES



INVASIVE DEVICES





Rule 7
Surgically invasive
- short term use

Rule 8
Surgically invasive
- long term use
- implant

UNLESS



UNLESS



Class B

Administers medicines

Class C

Undergoes chemical change in the body (excluding teeth)

Supplies ionizing radiation

Class C

Class C

Biological effect or absorbed

Class D

Direct contact with the central nervous system

Class D

Diagnose, monitor or correct - defect of heart or central circulatory system & in direct contact

Class D

Class C

Placed in the teeth

Class B

Direct contact with the heart or central nervous system or central circulatory system

Class D

Life supporting or life sustaining

Class D

Active implants

Class D

Biological effect or absorbed

Class D

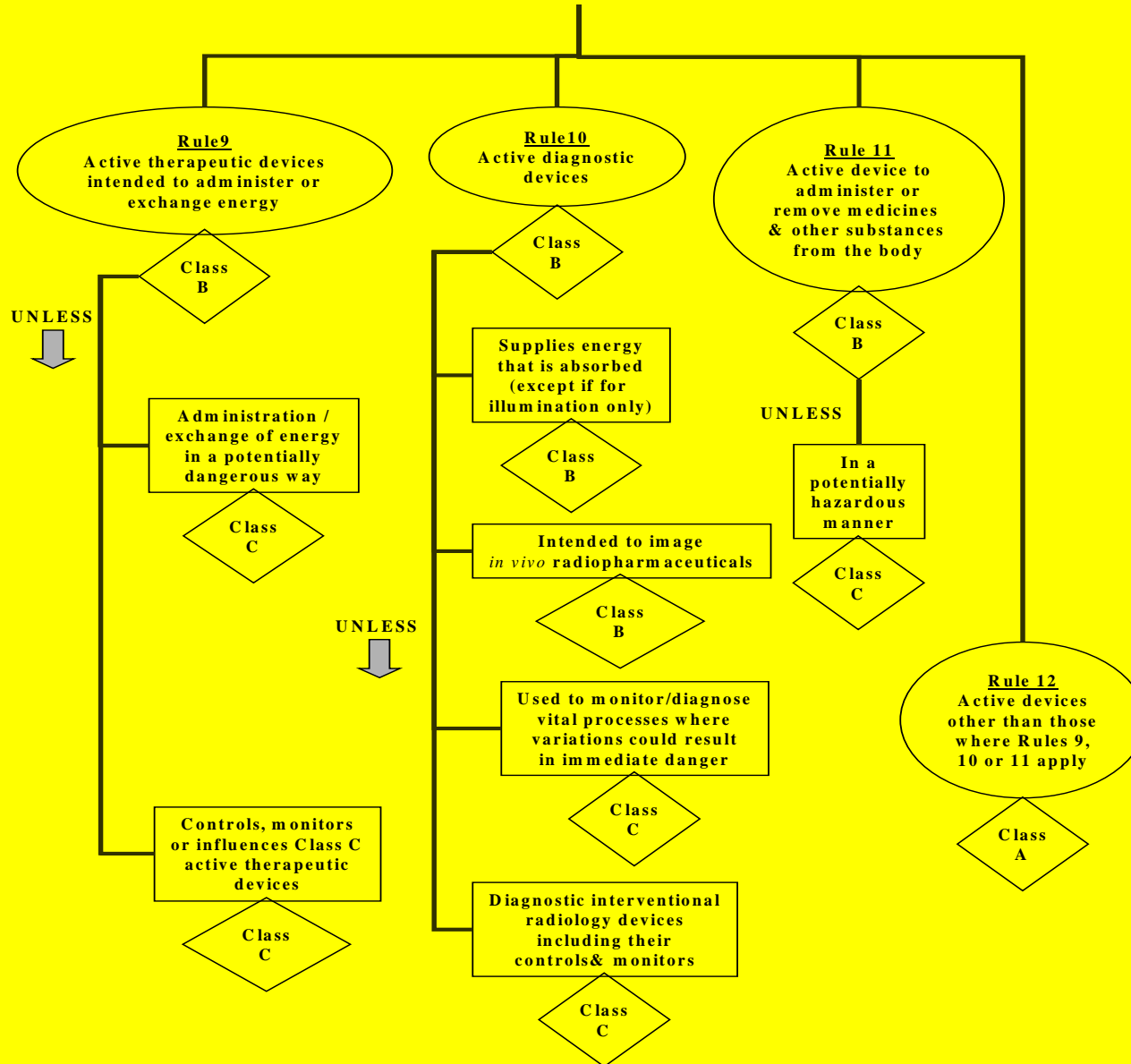
Administers medicines

Class D

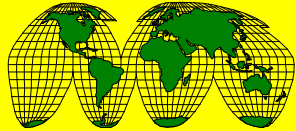
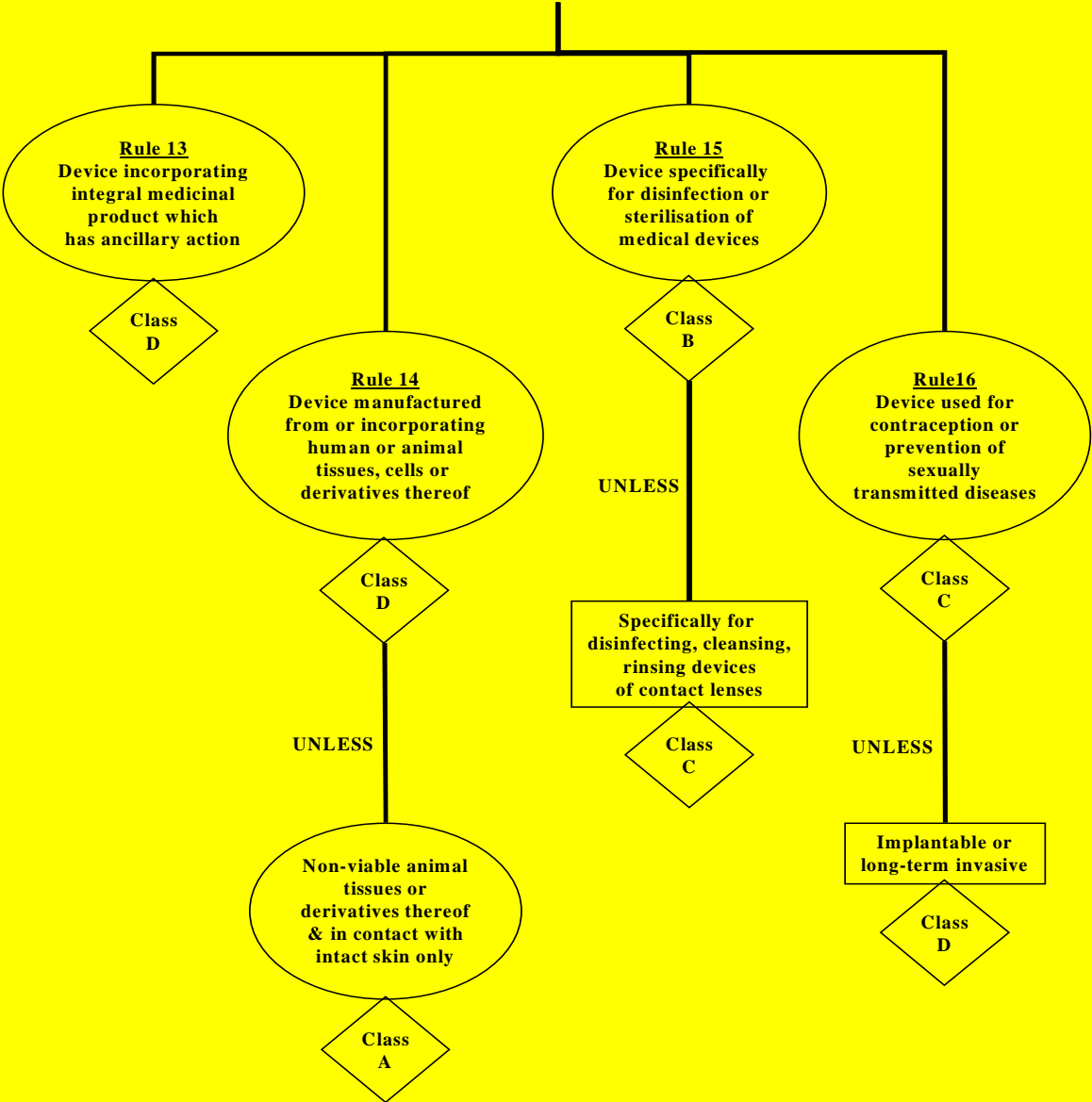
Undergoes chemical change in the body (excluding teeth)

Class D

ACTIVE DEVICES (ADDITIONAL RULES)



ADDITIONAL RULES



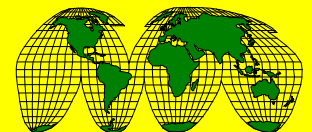


PROPOSED DOCUMENT
Global Harmonization Task Force

Title: Labelling for Medical Devices (including In Vitro Diagnostic Devices)

Authoring Group: Study Group 1 of the Global Harmonization Task Force

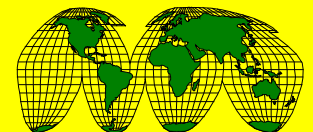
Date: November 21, 2001
08/05/02



For in vitro diagnostic medical devices:

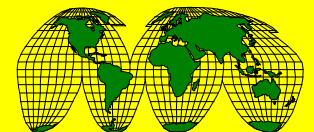
ab) Additional directions/instructions for the proper use of *in vitro* diagnostic medical devices which may include:

- Intended use (e.g. monitoring, screening or diagnostic) including an indication that it is for *in vitro* diagnostic use.
- Scientific test principle.
- Specimen type, collection, handling and preparation.
- Reagent description and any limitation (e.g. use with a dedicated instrument only).
- Assay procedure including calculations and interpretation of results.
- Information on interfering substances that may affect the performance of the assay.
- Analytical performance characteristics, such as sensitivity, specificity, accuracy (trueness and precision).
- Diagnostic performance characteristics, such as sensitivity and specificity.
- Reference intervals.
- The use of drawings and diagrams is highly recommended.



**AGENDA ITEM 7 – DISCUSS COMMENTS RECEIVED ON
PROPOSED DOCUMENT**

**INFORMATION DOCUMENT
CONCERNING THE DEFINITION OF
THE TERM ‘MEDICAL DEVICE’ –
SG1/NO029R11 OF 17 JANUARY 2002**

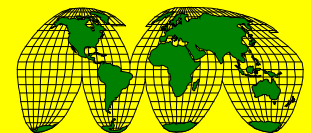


Medical device' means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,

providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmaco-logical, immunological or metabolic means, but which may be assisted in its function by such means.

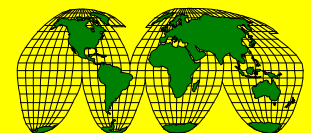


NOTE: An accessory is not considered to be a medical device. However, where an accessory is intended specifically by its manufacturer to be used together with the ‘parent’ medical device to enable the medical device to achieve its intended purpose, it should be subject to the same procedures and GHTF guidance documents as apply to the medical device itself.

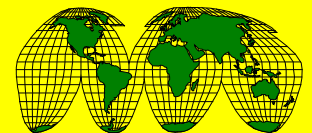
NOTE: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, reagents and the like may be covered by separate regulations.

NOTE: Products, which are considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- spare parts for medical devices,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but be subject to different controls.



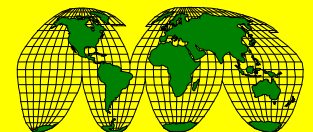
MAIN AGENDA ITEMS



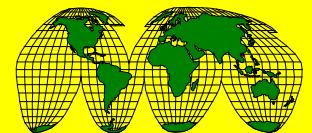
*Medical Devices Classification SG1/NO15R16 of 21
November 2001 – to note status of proposed
document, and review any comment received.*

*‘Global Approach to Pre-market Conformity
Assessment for Medical Devices SG1/NO40R5’
of 3 August 2001 – to review comments
received.*

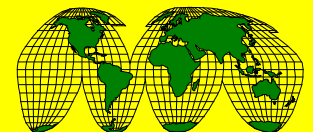
Harmonisation of clinical data needs in Conformity
Assessment



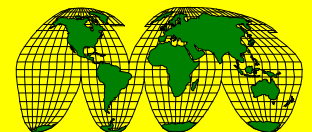
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) SG1/N011R16 of 18 December 2000 – to review progress with the pilot study and discuss any other matters related to the latest version of STED



Discuss proposal for amended version of
*Essential Principles of Safety and
Performance of Medical Devices*
(including specific additions to cover needs
of IVD's) SG1/N041R3 of 5 February 2002
and the comments received from
SG1 Members



To note proposed document on *Labelling
for Medical Devices (including IVD's)*
SG1/N043R3 of 21 November 2001

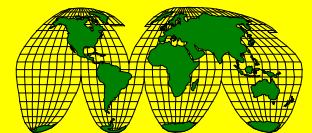


Review the following SG1 work: -

SG1 document on *Role of Standards in the Assessment of Medical Devices*, revised version taking account of IVD WG amendments

SG1 draft discussion document on *Classification of In Vitro Diagnostic Medical Devices* – to note present situation

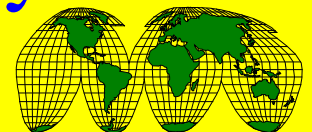
SG1 Committee draft on *Pre-market Conformity Assessment for Medical Devices* procedures (item 6) – provisions for IVD's



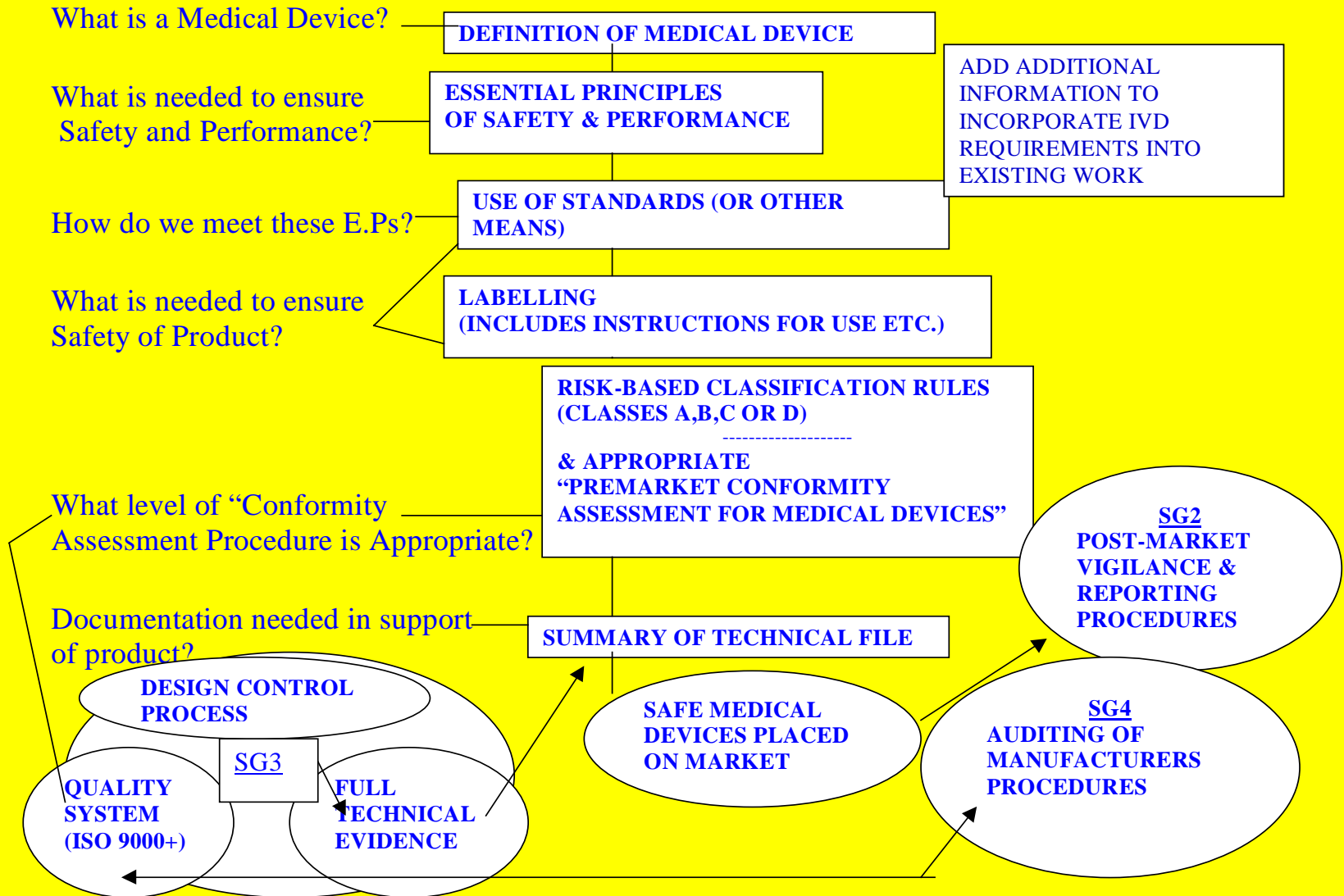
To note situation in relation to new Global
Medical Devices Nomenclature

Review any information on other
country/regional regulations or proposed
regulations. Include report from Asian
Harmonisation representative

Prepare for SG1 contribution to the Asian
Harmonisation Working Party



SCOPE OF GHTE-SG1 PREMARKET TECHNICAL REQUIREMENTS



What is a Medical Device?

DEFINITION OF MEDICAL DEVICE

What is needed to ensure Safety and Performance?

ESSENTIAL PRINCIPLES OF SAFETY & PERFORMANCE

How do we meet these E.P.s?

USE OF STANDARDS (OR OTHER MEANS)

What is needed to ensure Safety of Product?

LABELLING (INCLUDES INSTRUCTIONS FOR USE ETC.)

What level of "Conformity Assessment Procedure is Appropriate?

RISK-BASED CLASSIFICATION RULES (CLASSES A,B,C OR D)

 & APPROPRIATE "PREMARKET CONFORMITY ASSESSMENT FOR MEDICAL DEVICES"

Documentation needed in support of product?

SUMMARY OF TECHNICAL FILE

SG2
 POST-MARKET VIGILANCE & REPORTING PROCEDURES

DESIGN CONTROL PROCESS

QUALITY SYSTEM (ISO 9000+)

SG3

FULL TECHNICAL EVIDENCE

SAFE MEDICAL DEVICES PLACED ON MARKET

SG4
 AUDITING OF MANUFACTURERS PROCEDURES

ADD ADDITIONAL INFORMATION TO INCORPORATE IVD REQUIREMENTS INTO EXISTING WORK