INNOVATIVE BIOMARKERS FOR BETTER HEALTHCARE

IVDD – IVDR: Evolution of the Essential Requirements

Karin Hughes, Ph.D.

Vice President of Clinical & Regulatory Strategy, Astute Medical, Inc.

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Disclaimer and Good Practices

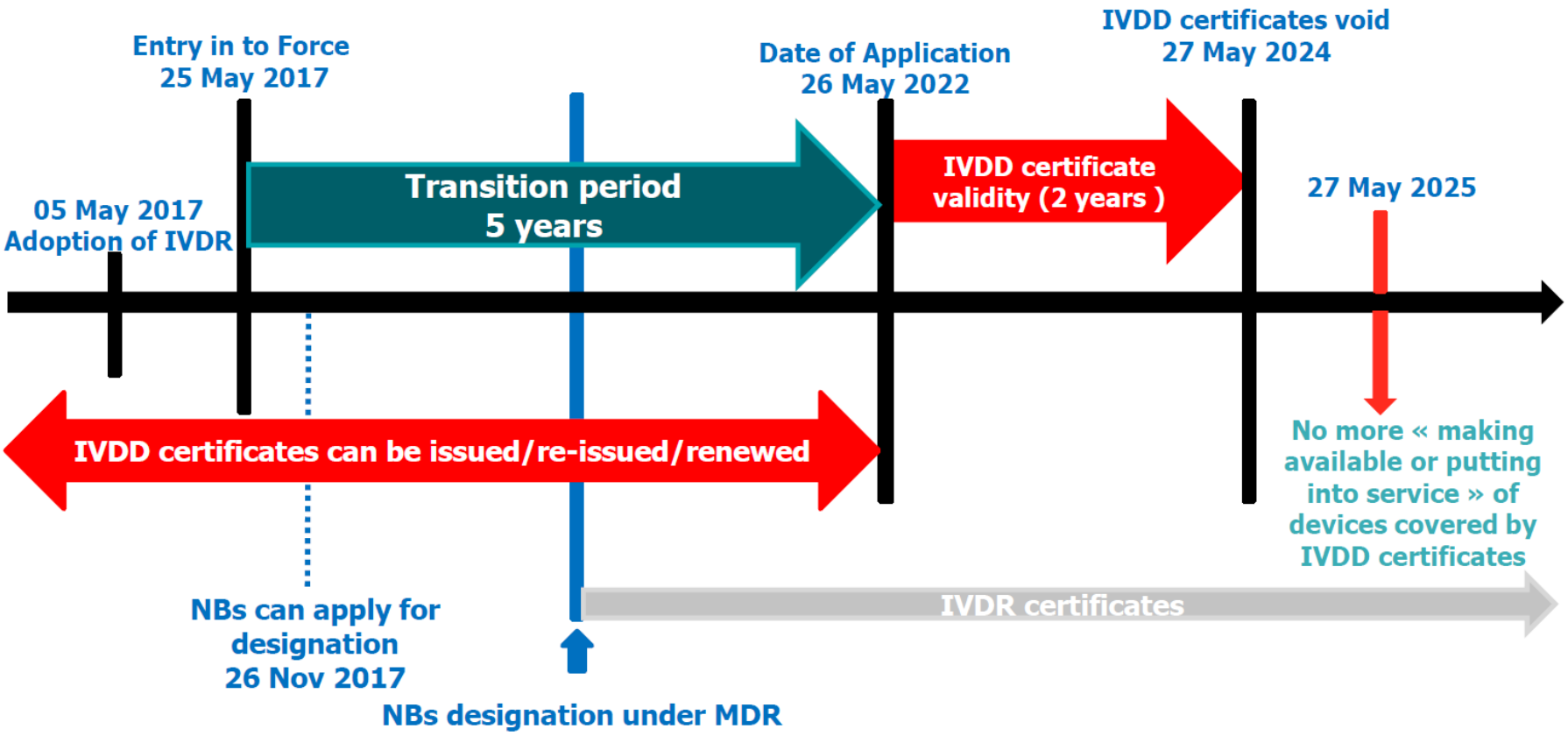
I am an employee of Astute Medical, Inc. This presentation contains my personal opinion and does not represent Astute Medical, Inc.'s viewpoints

The information provided herein is not meant to be comprehensive, but rather provide examples of paths forward for demonstrating conformity to the requirements and maybe some things to consider

Interpretations of the regulation are changing, as is the feedback we've been receiving from those organizations responsible for their implementation

And we are still waiting for Implementing Acts, Technical and Common Specifications, Guidance and so on….

IVDR Transition (Article 110) – the Clock is Ticking….



Adapted from British Standards Institute

General Safety and Performance Requirements Are Referred to Multiple Times in the IVDR

Article 5 **Placing on the market and putting into service**

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a performance evaluation in accordance with Article 56.

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, ….

6. In order to ensure the uniform application of Annex I, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 10 **General obligations of manufacturers**

2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

Article 57 **General requirements regarding performance studies**

1. The manufacturer shall ensure that a device for performance study complies with the general safety and performance requirements set out in Annex I apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

The General Safety & Performance Requirements are only a Fraction of All Considerations for "Placing on the Market and Putting into Service"

QMS Considerations (examples)

- Post market surveillance
- Vigilance
- Regulatory Compliance
- Economic Operators
- Person Responsible for Regulatory Compliance
- Clinical Evaluation & Investigation processes
- Unannounced Visits
- …

Technical Documentation Considerations (examples)

- Procedures for Technical Documentation
- Procedures for Clinical Evaluation
- SSCP & PSUR
- Labeling, UDI
- Change Management
- …

Other Considerations (examples)

- Device specific deliverables
- Software
- WEEE
- RoHS
- REACH/CLP
- …

Though the Requirements Are Modified the Path to Compliance is One We Know….

High Level Comparison of the IVDR General Safety & Performance Requirements & the IVDD Essential Requirements

IVDR General Safety & Performance Requirements	IVDD Essential Requirements
I. General Requirements	A. General Requirements
II. Requirements Regarding Performance, Design & Manufacture	B. Design & Manufacturing Requirements
III. Requirements Regarding Information Supplied with the Device	

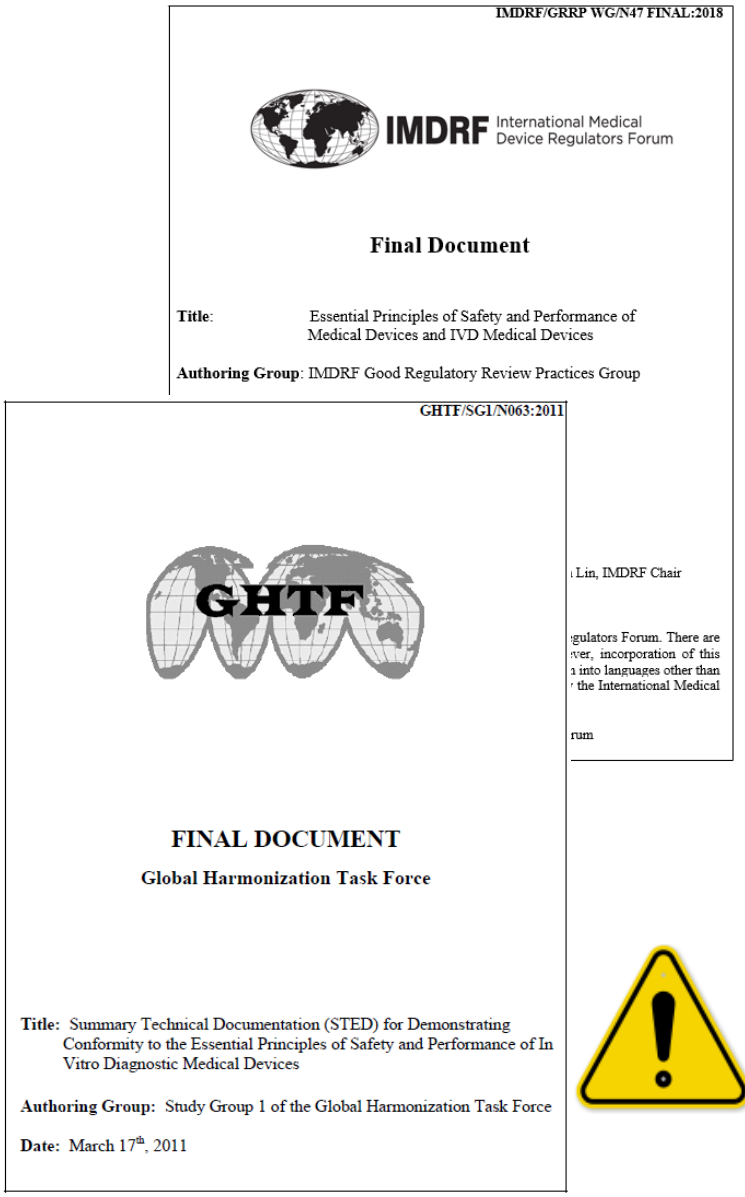
The IVDR still knows "essential requirements". However, they are now denoted "general safety and performance requirements". As pursuant to IVDD, manufacturers must provide evidence for their compliance with those requirements as part of conformity assessment procedures.

The Methodology to Showing Conformity is Still Sound….

Essential Requirements Checklist – IVDD

Global Harmonization Task Force (GHTF) was a voluntary group of representatives from national medical device regulatory authorities (such as the U.S. Food and Drug Administration (FDA)) and the members of the medical device industry whose goal was the standardization of medical device regulation across the world

International Medical Device Regulators Forum (IMDRF) has since assumed the mission of the GHTF


IMDRF/GRRP WG/N47 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices Group

GHTF/SG1/N063:2011

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

Title: Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

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

Date: March 17th, 2011

IMDRF: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices, 31 October 2018
GHTF Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety…17 March 2011

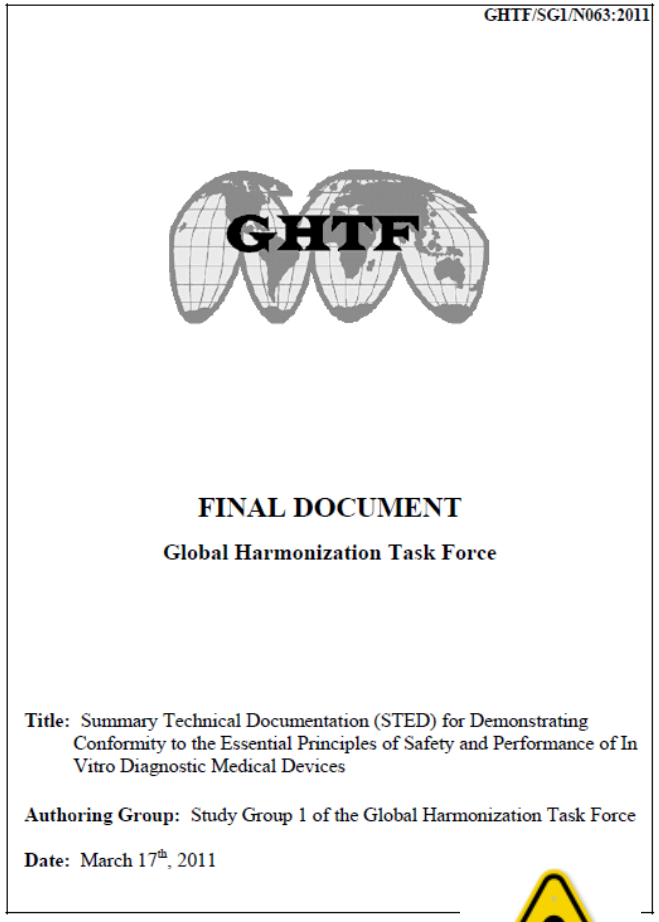
The Fundamental Principles Underlying Our Existing Essential Requirements Checklists May Be Used as a Basis for Conformity to the New General Safety & Performance Requirements

Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
Study Group 1 Proposed Document SG1(PD)/N011R20

Essential Principal Checklist	GHTF
Device:	

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
General Requirements			
5.1 Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			
5.2 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. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: ▪ identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, ▪ eliminate risks as far as reasonably practicable through inherently safe design and manufacture, ▪ reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, ▪ inform users of any residual risks.			

We Can Use Previous Guidance to Fill in Our Checklist…So Long as We Consider What's Changed


GHTF/SG1/N063:2011

GHTF

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Date: March 17th, 2011

Identify the IVD medical device

- Identify the IVD, and when applicable the various configurations/variants covered by the checklist

Applicable to device?

- Is the listed Essential Requirement applicable to the IVD medical device?
- Answer is 'Yes' or 'No'; If 'No' this should be briefly explained

Method used to demonstrate conformity & Method reference

- State the type(s) of method(s) that it has chosen to demonstrate conformity e.g., the recognised standard(s), industry or in-house test method(s), comparison study(ies) or other method used
- Title and reference the recognised standard(s), industry or in-house test method(s), comparison study(ies) or other method used to demonstrate conformity.
- For standards, this should include the date of the standard and where appropriate, the clause(s) that demonstrates conformity with the relevant EP.

Identify of Specific Documents (and location)

- reference to supporting controlled documents
- this column should contain the reference to the actual technical documentation that demonstrates conformity to the Essential Principle, i.e. the certificates, test reports, study reports or other documents that resulted from the method used to demonstrate conformity and, if included in the STED, its location.

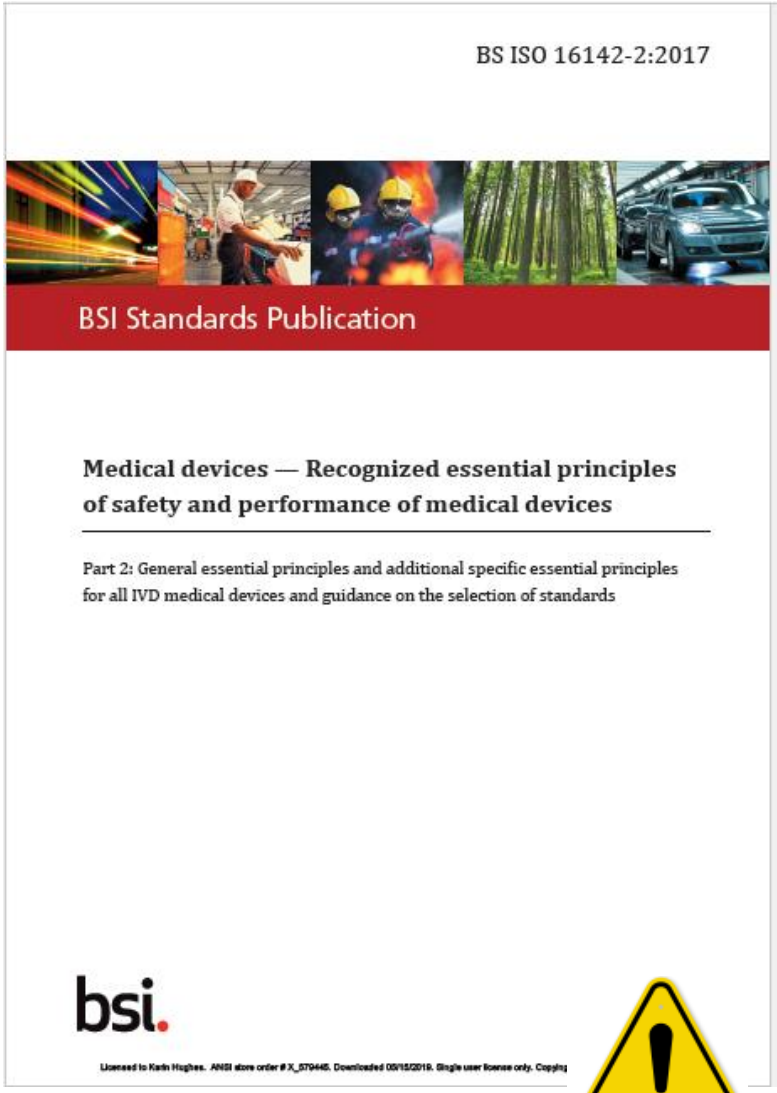
Methods and Method References

There are currently no harmonized versions of standards to support the IVD Regulation

Methods and method references used to demonstrate conformity have typically consisted of:

- recognised standard(s)
- industry or in-house test method(s)
- comparison study(ies)

ISO 16142-2:2017 "includes the essential principles of safety and performance, identifies significant standards and guides that can be used in the assessment of conformity of a medical device to the recognized essential principles that when met, indicate a medical device is safe and performs as intended…."



Methods and Method References

Types of guidance referred to include:

- General ISO Standards (e.g., ISO 13485, 14971, etc)
- Performance and evaluation standards (e.g., CLSI EP05, CLSI EP06, ISO 18153, etc)
- Instrumentation standards (e.g., IEC 61010-2-101, etc)
- Labeling standards (e.g., ISO 18113 (all parts))

Essential principle number	Essential principles of safety and performance of medical devices	References[a]
1	The medical device should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training and the medical and physical conditions of intended users, it will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with its use constitute acceptable risks when weighed against benefits to the patient and are compatible with a high level of protection of health and safety.	ISO 13485 ISO 14971 IEC 61010-2-101

IVDR General Safety & Performance Requirements (GSPRs)

Per Article 5 of the IVDR, all IVDs need to meet the requirements of the GSPRs

- Includes devices manufactured & used within health institutions
- Performance evaluation devices – certain requirements apply
- Required under Article 5 & outlined under Annex I

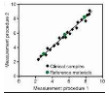
The manufacturer of an in vitro diagnostic (IVD) device is expected to design and manufacture a product that is safe and effective throughout its life-cycle – the GSPRs outlines these principles as requirements

Manufacturers must provide evidence for their compliance with those requirements as part of conformity assessment procedures

Resembles the Essential Requirements under the IVDD – fundamental concept is not significantly different

- Number of requirements and level of detail have increased
  - IVDD: 13 area divided into 2 chapters
  - IVDR: 20 areas divided into 3 chapters
- Changes from the ERs
  - More logical naming or arrangement in the IVDR than in the IVDD
  - Requirements defined in more detail or are more specific in the IVDR than in the IVDD
  - Former requirements for self testing have a broader scope and apply to devices for near-patient testing

IVDR General Safety & Performance Requirements Overview

1. Safe, Perform as Intended, State of the Art 
2. Risk Reduction as far as possible
3. Risk Management 
4. Risk Control Measures
5. Risk of Use Error (Residual Risks) 
6. Safe over Lifetime 
7. Packaging, Storage, Transport  
8. Undesirable side-effects minimized: Risks < Benefits 
9. Performance & Traceability (including near patient or self-test)  
10. Chemical, Physical & Biological Properties
11. Infection & Microbial Contamination 

12. Devices incorporating materials of biological origin 
13. Construction of devices and interaction with their environment
14. Devices with a measuring function 
15. Protection against radiation 
16. Electronic programmable systems – devices that incorporate electronic programmable systems & software that are devices in themselves 
17. Devices connected to or equipped with an energy source 
18. Protection against mechanical and thermal risks 
19. Protection against the risks posed by devices intended for self-testing or near patient testing 
20. Information Supplied  

Chapter I: GENERAL REQUIREMENTS (1-8)
Chapter II: REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFACTURE (9-19)
Chapter III. REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE (20)

Our Aim is to Demonstrate Conformity to the General Safety & Performance Requirements – Example Checklist

General Safety and Performance Checklist	
Device:	

General Safety and Performance Requirement	Applicable to the device?	Method of Conformity	Identity of Specific Documents
Chapter I General Requirements			
1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.			
2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.			
3. Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall: (a) establish and document a risk management plan for each device; (b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the benefit-risk ratio and risk acceptability; and (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.			

Note: it is manufacturer's sole responsibility to choose appropriate conformity assessment processes and documentation methods

Getting Started - The Approach We're Taking….Step 1

1. Perform a gap assessment between the IVDR General Safety and Performance Requirements and the IVDD Essential Requirements
   - What's identical or nearly identical?
   - What's more stringent under the IVDR?
   - What's brand new under the IVDR?

Note: it is manufacturer's sole responsibility to choose appropriate conformity assessment processes and documentation methods

Exploring the Relationship between the IVDR General Safety and Performance Requirements and the IVDD Essential Requirements

WHITE PAPER

EXPLORING THE RELATIONSHIP BETWEEN THE IVDR AND THE IVDD

General Safety and Performance Requirements Versus Essential Requirements

This tool clarifies the corresponding relationships between the general safety and performance requirements, as defined in Annex I of the EU in vitro diagnostic medical device regulation 2017/746 (IVDR) and the Essential Requirements defined in Annex I of the EU Directive 98/79/EC for in vitro diagnostic medical devices (IVDD). Use this tool to ensure your in vitro diagnostic medical devices satisfy all the applicable general safety and performance requirements to demonstrate conformity with the IVDR.

Cool tool!

….but there are a few "typos" so you still need to proceed with caution and use your own judgement

Ultimately the conformity assessment responsibility is yours….

COLOR INTERPRETATION		
Green		Requirements between the IVDD and IVDR are either identical, or very similar
Yellow		IVDR requirements are more stringent than IVDD requirement
Orange		IVDR requirement has no equivalent in the IVDD

Tool developed by and available at NSF International - http://www.nsf.org/newsroom_pdf/md_wp_ivdr.pdf

Excerpt from the NSF Tool – Risk, Risk Control Measures & Lifetime

More Stringent

New in IVDR

More Stringent

New in IVDR

Nearly Identical

IVDR REF		REQUIREMENT	IVDD REF	REQUIREMENT
4(a)		Eliminate or reduce risks as far as possible through safe design and manufacture;	A.2 Bullet 1	…eliminate or reduce risks as far as possible (inherently safe design and construction) …
4(b)		Where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and	A.2 Bullet 2	…where appropriate take adequate protection measures in relation to risks that cannot be eliminated…
4(c)		Provide information for safety (warnings/precautions/ contra-indications) and, where appropriate, training to users.		New to IVDR
4		Manufacturers shall inform users of any residual risks.	A.2 Bullet 3	…inform users of the residual risks due to any shortcomings of the protection measures adopted…
5		In eliminating or reducing risks related to use error, the manufacturer shall:		New to IVDR
5(a)		Reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and		New to IVDR
5(b)		Give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).		New to IVDR
6		The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	A.4	The characteristics and performances referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patient or the user and, where applicable, of other persons, are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.

The Approach We're Taking….Step 2…Example Quantitative Test

2. Determine if the IVDR General Safety and Performance Requirements apply or not (and if they do not apply, document your rationale)

IVDD Ref	IVD Directive 98/79/EC	IVDD Applies Yes/No	IVDR Ref	IVDR Regulation (EU) 2017/746	IVDR Applies Yes/No	Impact *No Change, Change, New*
B.2.3	2.3 Devices labelled either as 'STERILE' or as having a special microbiological state must be designed, manufactured and packed in an appropriate pack, according to procedures suitable for ensuring that they remain in the appropriate microbiological state indicated on the label when placed on the market, under the storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened. >> **Rationale: The device is not designated as "sterile" or as having a special microbiological state.**	No	11.2	11.2. Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.	No	No Change
B.2.4	2.4 Devices labelled either as 'STERILE' or as having a special microbiological state must have been processed by an appropriate, validated method. >> **Rationale: The device is not designated as "sterile" or as having a special microbiological state**	No	11.3	11.3. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	No	Change
B.2.5	2.5 Packaging systems for devices other than those referred to in section 2.3 must keep the product without deterioration at the level of cleanliness indicated by the manufacturer and, if the devices are to be sterilised prior to use, reduce as far as possible the risk of microbial contamination. Steps must be taken to reduce as far as possible microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.	Yes	11.5	Partially covered in 11.5. No equivalent found in IVDR	Yes	Change

Note: it is manufacturer's sole responsibility to choose appropriate conformity assessment processes and documentation methods

The Approach We're Taking….Step 3…Example Quantitative Test

3. For those that do apply conduct an impact assessment
   - Is it identical or nearly identical? If yes, consider impact to existing:
     - Method(s) used to demonstrate conformity (standards)
     - Method reference(s) (aka output used for objective evidence)
     - Reference to supporting controlled documents
   - Is it more stringent or brand new under the IVDR? If yes, you may have to provide (add):
     - Methods to demonstrate conformity
     - Method references (aka output used for objective evidence)
     - References to supporting controlled documents – and this may be something you have to generate!

But What If? *(Legacy Devices)*

Legacy Devices

- *Term is not defined*
- *We know there is no grandfathering*
- *GSPRs need to be met*

Annex XIII Part A,1.2.2. Demonstration of the analytical performance

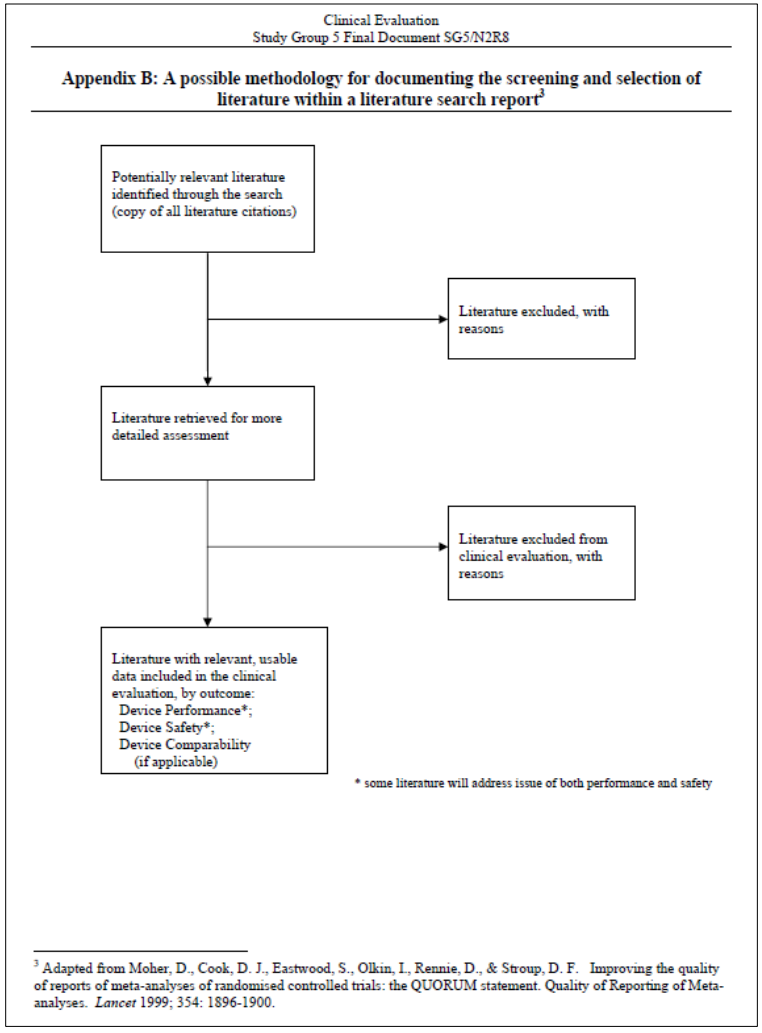
- The manufacturer shall demonstrate the analytical performance of the device in relation to all the parameters described in point (a) of Section 9.1 of Annex I, unless any omission can be justified as not applicable.
- As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.
- For novel markers or other markers without available certified reference materials or reference measurement procedures…if there are no comparative methods, different approaches may be used …such as comparison to some other well-documented methods or the composite reference standard.
- In the absence of such approaches, a clinical performance study comparing performance of the novel device to the current clinical standard practice is required.

Annex XIII Part A, 1.2.3. Demonstration of the clinical performance

- The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable.
- Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:
  - clinical performance studies;
  - scientific peer-reviewed literature;
  - published experience gained by routine diagnostic testing.
- Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.

Note: it is manufacturer's sole responsibility to choose appropriate conformity assessment processes and documentation methods

But What If? *(Legacy Devices)* – *Options?*



Clinical Evaluation
Study Group 5 Final Document SG5/N2R8

Appendix B: A possible methodology for documenting the screening and selection of literature within a literature search report[3]

Potentially relevant literature identified through the search (copy of all literature citations)

→ Literature excluded, with reasons

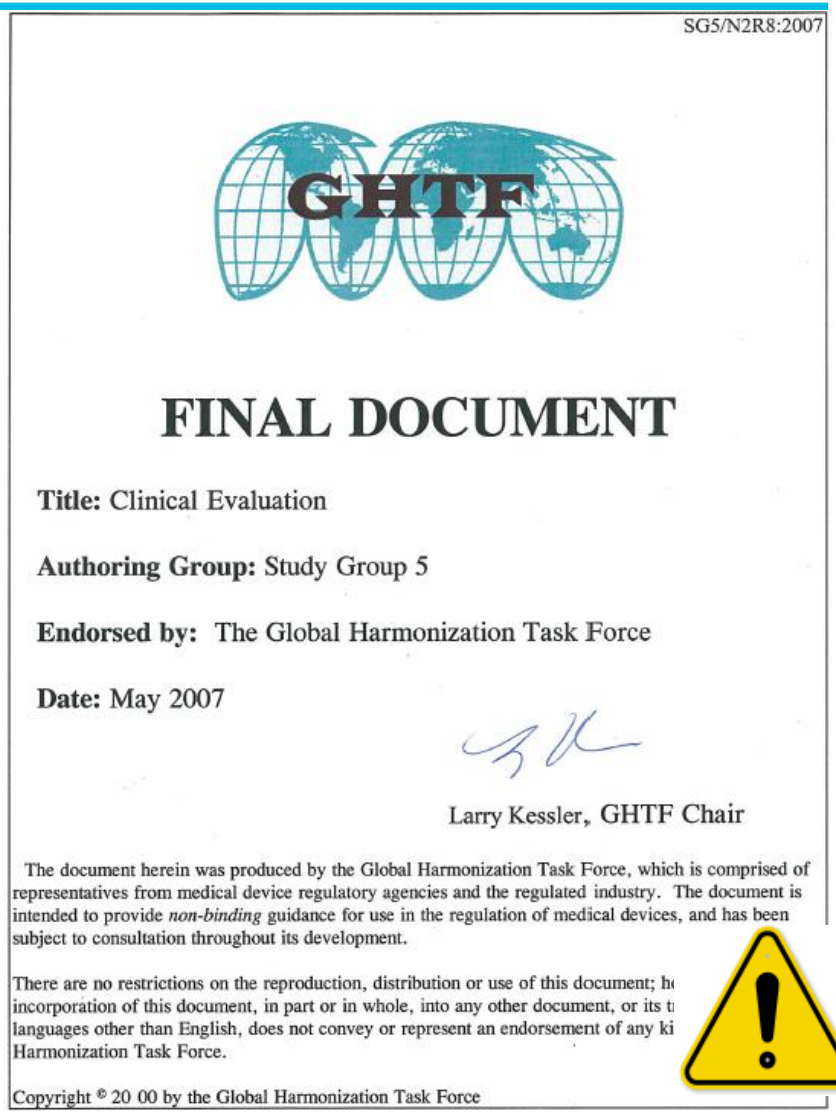
Literature retrieved for more detailed assessment

→ Literature excluded from clinical evaluation, with reasons

Literature with relevant, usable data included in the clinical evaluation, by outcome:
Device Performance*;
Device Safety*;
Device Comparability (if applicable)

* some literature will address issue of both performance and safety

[3] Adapted from Moher, D., Cook, D. J., Eastwood, S., Olkin, I., Rennie, D., & Stroup, D. F. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUORUM statement. Quality of Reporting of Meta-analyses. *Lancet* 1999; 354: 1896-1900.



SG5/N2R8:2007

GHTF

FINAL DOCUMENT

Title: Clinical Evaluation

Authoring Group: Study Group 5

Endorsed by: The Global Harmonization Task Force

Date: May 2007

Larry Kessler, GHTF Chair

The document herein was produced by the Global Harmonization Task Force, which is comprised of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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Note: it is manufacturer's sole responsibility to choose appropriate conformity assessment processes and documentation methods

Summary of Steps That May be Used to Create a General Safety & Performance Checklist

Map differences between the IVDR General Safety and Performance Requirements and the IVDD Essential Requirements

Determine Applicability of Requirements to Each Device

Conduct Impact Assessment on Existing Methods of Conformity, Specific Documents (outputs) and their Locations

Fill (any) Gaps

Document Checklist Demonstrating Conformity to Applicable Requirements

Note: it is manufacturer's sole responsibility to choose appropriate conformity assessment processes and documentation methods

A Few Notes About Risk

There are many new requirements related to risk management under the IVDR General Safety and Performance Requirements when compared to the IVDD Essential Principles

Annex I, Chapter 1, 3 establishes a legal requirement to implement a risk management system, including a risk management plan and requirements for a post-market surveillance system

Requirements are detailed and align well with ISO 14971, however, there is no requirement to rely upon ISO 14971 (Note: ISO 14971 is under revision*)

Annex I, Chapter 1, 4 sets requirements related to risk reduction and controls for residual risks….

Annex I, Chapter 1, 5 (a)(b) require eliminating or reducing risks related to use errors by establishing new requirements related to ergonomic factors and use environment considerations in the design and risk management of products

Annex I, Chapter 2, 13.2(d) sets new requirements related to risks due to software and the IT environment within which it operates and interacts

- consider including methods related to software development cycles, e.g., IEC 62304

And, yes, risk impacts labeling requirements, e.g., Annex I, Chapter 3, 20.1(d) including the need for the determination and communication of residual risks

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

*changes include detailed requirements around evaluating residual risks and collecting production and post-production information; and refocuses the standard on benefit-risk evaluation, which is in line with changing regulatory requirements in the In Vitro Diagnostic Regulation (IVDR)). The new ISO 14971 has three informative annexes, with the other seven incorporated into TR 24971

A Few Notes About Labeling Requirements – Information Supplied

There are many new requirements for what information is to be included on the label and in the instructions for use under the IVDR (General Safety and Performance Requirements: Chapter III Requirements Regarding Information Supplied with the Device) when compared to the IVDD.

In many cases, the IVDR makes requirements that are found in the ISO 18113 series (and therefore may be already common practice) explicit.

There are also many new requirements, including (but not limited to):

- Addition of UDI (unique device identifier)
- Elements related to intended purpose (think about this in the context of controls, instruments, etc)
- Information on the label – the details strictly necessary for a user to identify the device, and where it is not obvious for the user, the intended purpose of the device
- Maintenance of electronic instructions for use on the manufacturer's website
- Use of symbols is still supported, but "any symbol…shall conform to the harmonized standards or common specifications"
- Requirements for labeling for hazardous substances which are carcinogenic, mutagenic, or toxic for reproduction, endocrine disruptors or sensitizers
- New disposal requirements – design & development to facilitate safe disposal of the device…
- Requirements for self-testing and near patient testing
- Labeling requirements for software (e-labels on start up screens?)
- Batch to batch variation (maximum self-allowed due to calibration value assignment methodology…)
- Requirements for information supplied to the user to be in the official languages determined by the Member State in which the device is made available to the user or patient (Article 10 General Obligations of Manufacturers)

Goals and a Reality Check - Things We Did (and Did Not) Discuss Today

Goals

- Making the transition to the new requirements
- Understanding and closing the gaps
- Risk benefit and labelling and GSPRs

But Wait There's More!

- Classification and the rest of the Conformity Assessment Procedures
- QMS gaps (e.g., post market surveillance, economic operators, unannounced visits, etc)
- Technical Documentation requirements
- ……

Conclusions

The General Safety and Performance Requirements (Annex I) apply to all IVDs in order to conform and apply the CE mark under the IVDR

Requirements are dependent on the device, therefore, gap assessments are needed of all existing devices to transfer to the IVDR

The fundamental principles underlying our existing Essential Requirements Checklists might be useful as a basis for conformity to the New General Safety & Performance Requirements

There are more requirements, but not all are new and there may be creative means to close (any) gaps

Tools are available (Google!!) and may be utilized to jump-start your gap & conformity assessments, but you are ultimately responsible for ensuring the suitability and accuracy of what you use

New IVDs and existing CE-marketed IVDs will need to comply with these requirements by 26 May 2022 (end of transtion period), manufacturers should be aggressively preparing now