IMDRF IVD WG活動報告

医薬品医療機器総合機構（PMDA）
体外診断薬審査室
山田宏美

概要

1. IVD WGについて
2. 「IVDのクラス分類原則」文書改訂内容
3. 今後の予定

1．IVD WGについて

IVD WGについて

【背景・概要】

- 2019年3月のIMDRF MC会合でNWIPとして、ロシアRoszdravnadzorより、GHTF/SG1/N45:2008「IVD のクラス分類原則」文書改訂が提案され、承認された。
- 当該文書発出から10年が経ち、新しい技術（コンパニオン診断薬、遺伝子検査、SaMDなど）が多く開発されており、これらに対応するための改訂

参加国

- オーストラリア（TGA）
- ブラジル（ANVISA）
- カナダ（Health Canada）
- 中国（NIFDC）
- European Union
（ドイツ；PEI、フランス；ANSM、ベルギー；EC）
- 日本（MHLW/PMDA）
- ロシア
（Roszdravnadzor）；議長
- 韓国（MFDS）
- シンガポール（HSA）
- 米国（FDA）
- WHO
- AHWP
- PAHO
- GMTA

F2F会議

【開催日・場所】

2019年8月20日～22日　ロシア・モスクワ

【結果】

- 10年前に作成されたガイドラインの記載について、現在の視点からみて解釈が不明確な点を洗い出し、最近の承認審査の経験に基づき、修正案について議論した。
- 近年改訂が行われた他のIMDRF文書、EU IVDR、ISOの記載を参照し、整備が行われた。

Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IMDRF/IVD WG (PD1)/N64)

- 2020年3月　MCにパブコメ文書案を提出、承認
- 2020年7月　パブコメ終了、コメント対応
- 2021年1月　MCに最終文書案を提出、承認

2．「IVDのクラス分類原則」文書改訂内容

3.0 References

IMDRF/GRRP WG/N47FINAL:2018
Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

IMDRF/GRRP WG/N52FINAL:2019
Principles of Labelling for Medical Devices and IVD Medical Devices

IMDRF/SaMD WG/N10FINAL:2013
Software as a Medical Device (SaMD): Key definitions

IMDRF/SaMD WG/N12FINAL:2014
Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations

3.0 References

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*

ISO/IEC Guide 51:2014 *Safety aspects – Guidelines for their inclusion in standards*

ISO 18113-1:2009 *In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements.*

4.0 Definitions

Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices

- **Accessory for an IVD Medical Device**
- **Companion Diagnostics Medical Device**

ISO 18113-1: 2009

- **Calibration**
- **Control Materials**
- **Intended User**

IMDRF/SaMD WG/N12FINAL:2014, N10FINAL: 2013

- **Critical Situation**
- **Software as a Medical Device (SaMD)**

IMDRF/GRRP WG/N47FINAL: 2018

- **Lay User**
- **Self-testing IVD Medical Device**

5.0 General Principles

（削除）

Certain jurisdictions may lower the classification of IVD medical devices for which traceability is established through the use of reference measurement procedures and/or available reference materials.

6.0 Recommendations and Factors Influencing IVD Medical Device Classification

- Software as a Medical Device (SaMD) for IVD should be classified based on its intended diagnostic purpose, with consideration given to provisions in the document "*Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations*" (IMDRF/SaMD WG/N12FINAL:2014).

7.0 Proposed General Classification System for IVD Medical Devices（改訂前）

Figure 1: Proposed general classification system for IVD medical devices.

CLASS	RISK LEVEL	EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyser , prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy self testing, Anti-Nuclear Antibody, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self testing, HLA typing, PSA screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

7.0 Proposed General Classification System for IVD Medical Devices（改訂後）

Figure 1: Proposed general classification system for IVD medical devices.

		PUBLIC health risk		
		Low	*Moderate*	*High*
INDIVIDUAL health risk	*Low*	**A**	***N/A****	***N/A****
	Moderate	**B**	**B or C**	**C or D**
	High	**C**	**C**	**D**

* ***N/A*** *means there is no such IVD medical device*

9.0 Classification Rules

Rule 3: IVD medical devices are classified as **Class C** if they are intended for use:

- in detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested or to the individual's offspring.
- in screening, diagnosis or staging of cancer
- in screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

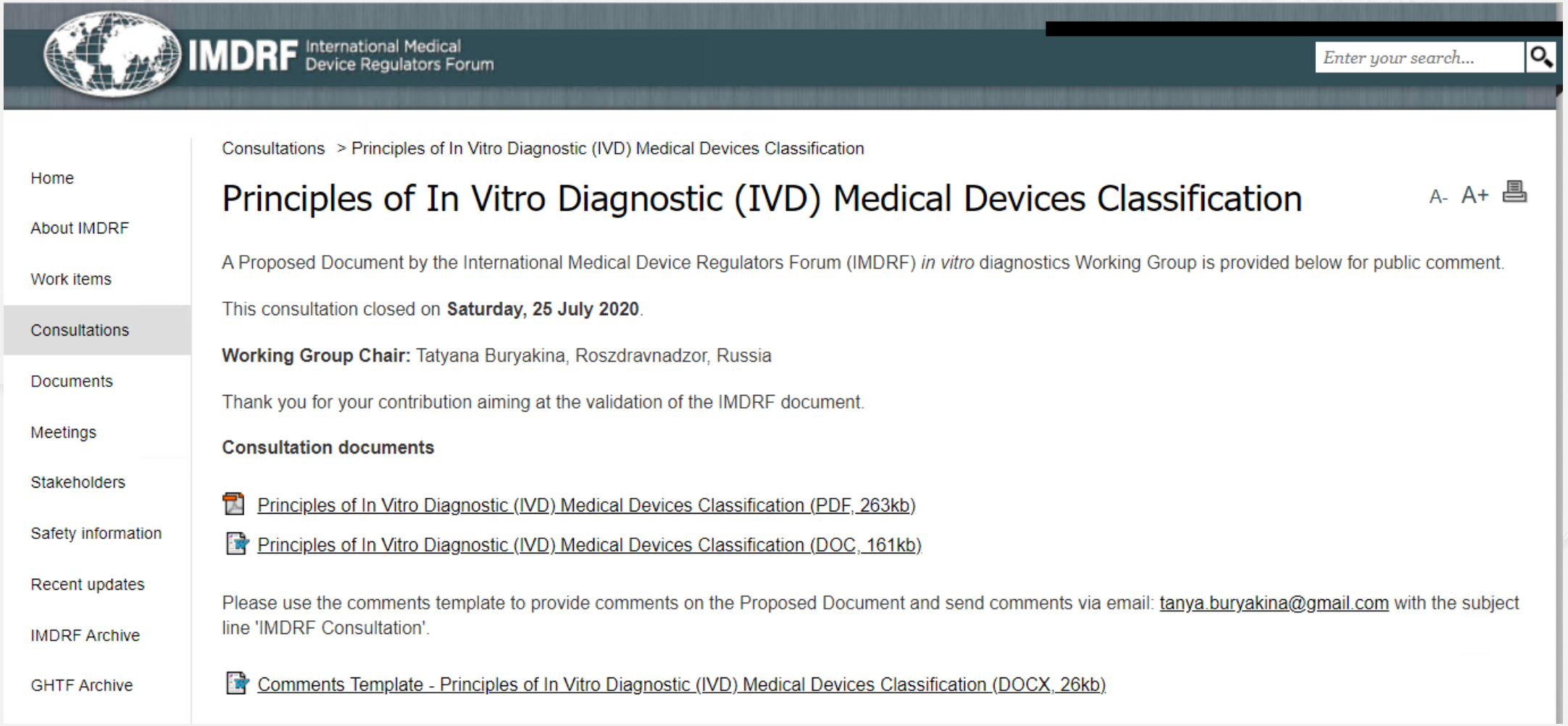
9.0 Classification Rules

Rule 5: The following IVD medical devices are classified as **Class A**:

Examples;

Selective/differential microbiological General culture media, identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

http://www.imdrf.org/consultations/cons-n64-principles-ivd-mdc.asp



IMDRF International Medical Device Regulators Forum

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Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

A- A+

A Proposed Document by the International Medical Device Regulators Forum (IMDRF) *in vitro* diagnostics Working Group is provided below for public comment.

This consultation closed on **Saturday, 25 July 2020**.

Working Group Chair: Tatyana Buryakina, Roszdravnadzor, Russia

Thank you for your contribution aiming at the validation of the IMDRF document.

Consultation documents

Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (PDF, 263kb)

Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (DOC, 161kb)

Please use the comments template to provide comments on the Proposed Document and send comments via email: tanya.buryakina@gmail.com with the subject line 'IMDRF Consultation'.

Comments Template - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (DOCX, 26kb)

3．今後の予定

NWIEについて

- GHTF時代に作成されたN6-8の手順書の改訂提案。
- 2021年3月、6月、9月会合で議論され、承認された。

NWIEについて

N6: IVD医療機器に係るクリニカルエビデンス

GHTF/SG5/N6 (Clinical Evidence for IVD Medical Devices-Key Definitions and Concepts)

N7: 科学的妥当性の決定及びパフォーマンスの評価

GHTF/SG5/N7 (Clinical Evidence for IVD Medical Devices-Scientific validity determination and Performance Evaluation)

N8: IVD医療機器に係るクリニカルパフォーマンススタディー

GHTF/SG5/N8 (Clinical Evidence for IVD Medical Devices-Clinical Performance studies for IVDs)

まとめ

- 近年改訂された文書及び科学技術等を踏まえ、GHTF/SG1/N45:2008「IVD のクラス分類原則」文書が改訂された。
- 今後、臨床評価に係るN6-8の手順書の改訂が実施される予定。