Regulatory Updates

Office of Standards and Compliance for Medical Devices,
Division of Registered Certification Body Assessment,
Pharmaceuticals and Medical Devices Agency (PMDA)

Topic

- Change of MO169

History of MO169

2004	MHLW Ministerial Ordinance No. 169 (2004), titled “Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents” was initially enacted in 2004. The purpose of the establishment was to make Medical Device QMS requirements be harmonized to ISO13485:2003. Although the requirements are substantially equivalent to ISO13485, it included many additional requirements characteristic to Japan.
2014	The initial version was revised to be more aligned to ISO13485:2003. The number of special requirements are reduced. The requirements from ISO13485 are placed in chapter 2 and the additional requirements are moved to chapter 3.
2017	A new chapter (chapter 5-2), which specifies the requirements for manufacturers of R-SUD, was added to the ordinance.
2016-2019	Since ISO13485:2016 was issued in 2016, discussion to revise the ordinance was started between the industry and the regulatory authorities. They have agreed to revise it to be aligned to ISO13485:2016 and draft making was conducted.
2020 fall	Public comment to the revised ordinance was conducted from October 16 to November 16.

Summary of the change

Title

The name of the ordinance is planned to be maintained.

Ex. MO169(2004), revised by MO155(2020) →

MO169(2004), revised by MOXXX(2021)

Contents

- **Chapter 2 (requirements aligned to ISO13485)**

Chapter 2 of the ordinance is going to be harmonized to ISO13485:2016.

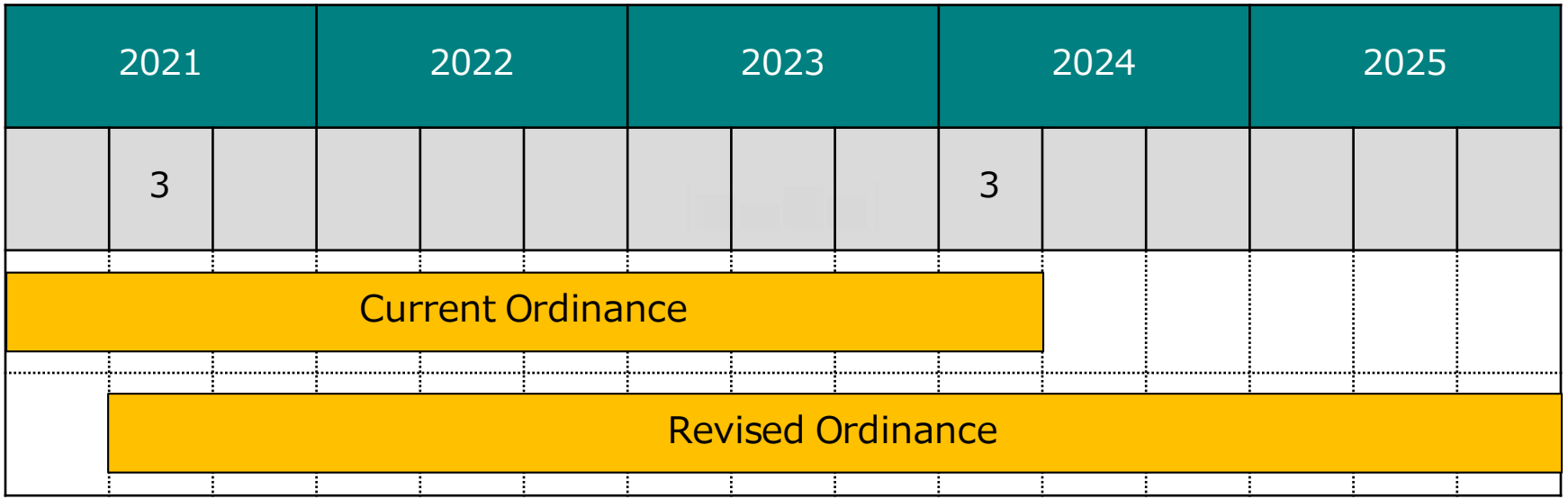
- **Chapter 3 (requirements characteristic to Japan)**

A requirement is planned to be deleted. None of new requirement is planned to be added.

Image of the change

Current Ordinance	New Ordinance
Chapter 1: Purpose, Definition of Terms, and Scope of Application	Chapter 1: Purpose, Definition of Terms, and Scope of Application
Chapter 2: Basic Requirements aligned to ISO13485:2003	Chapter 2: Basic Requirements aligned to ISO13485:2016
Chapter 3: Additional Requirements	Chapter 3: Additional Requirements
Chapter 4, 5, and 5-2: Product Specific Requirements (Biological Products, Radioactive IVDs, SUD)	Chapter 4, 5, and 5-2: Product Specific Requirements (Biological Products, Radioactive IVDs and R-SUD)
Chapter 6: Others	Chapter 6: Others

Transition Period



- MHLW is planning to release the revised ordinance in March 2021.
- The transition period is planned to be three years.
- Old and new ordinance is expected to co-exist until Q1 2024 on the assumption above.

Impact on MDSAP

The following MDSAP documents will be revised..

- MDSAP AU P0002 Audit Approach,
- MDSAP AU F0019.1 Medical Device Regulatory Audit Report,
- MDSAP AU G0019.4 Nonconformity Grading and Exchange Form, and

Others..

Revision of Audit Report Format

During the transition period, manufacturers can select either New or Old ordinance as audit criteria. The AOs are going to be required to clarify which ordinance is used as criteria.

Section 3. Certification Schemes, Scopes & Criteria, Audit Types

MDSAP Certification Scheme ☐ Not Applicable

Audit type
◉ Initial ○ Surveillance #1 ○ Surveillance #2 ○ Recertification ○ Special ○ Unannounced ○ Mock
Specify

Scope of certification

Is any device-drug or device-biologic combination included in the scope of certification? ○ Yes ○ No

☒ **ISO 13485** ○ 2003 ◉ 2016

☐ **Australia**

☐ **Brazil**

☐ **Canada**

☒ **Japan**
○ MHLW Ministerial Ordinance No.169 (2004) amended by MHLW Ordinance No.155 (2020) Articles 4 to 68
◉ MHLW Ministerial Ordinance No.169 (2004) amended by MHLW Ordinance No. XXX (2021) Articles 4 to 68
Japan PMD Act (as applicable)

☐ **United States**

Other reference doc.

Image

Revision of Audit Approach

Example (audit approach):

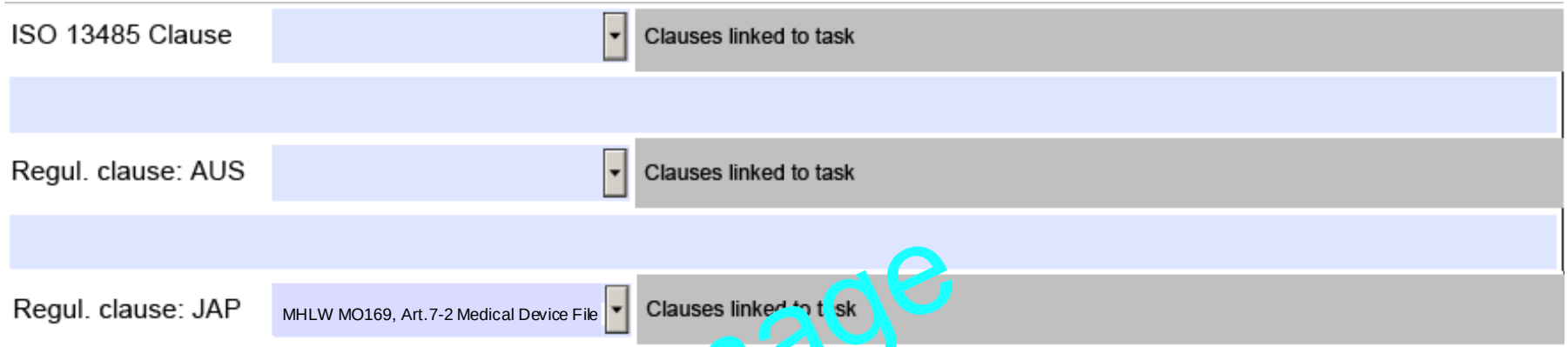
Audit Tasks and Links to Other Processes:

1. Confirm that quality management system planning is performed to ensure that all required processes are identified, documented, implemented, monitored and maintained in order to conform to the applicable requirements and meet quality objectives. Verify that changes to the quality management system are managed to maintain the conformity of the quality management system and of the devices produced. Verify that a quality manual has been documented.

Clause and Regulation: [ISO 13485:2016: 4.1.1, 4.1.2, 4.1.3, 4.2.2, 4.1.4, 5.4.2; TG(MD)R Sch3 P1 1.4(4); RDC ANVISA 16/2013: 2.1, 5.6; MHLW MO169: (2021) 5, 7, 14, (2020) 5, 8; 21 CFR 820.20]

Revision of NC grading form

The text of the new and old ordinance will be embedded in the NCGF.



Image

MO169(2021)
7-2 Medical device file
For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.
The content of the file(s) shall include, but is not limited to:
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Materials planned to be provided

- Comparison table between ISO13485:2016 and chapter 2 of the new ordinance
- Translation of chapter 3 of the new ordinance
- A Material for Training (optional)

The AOs are expected to train their auditors for the change of the requirements by themselves.

Conclusion

- MO169 is planned to be changed in March 2021. The AOs are expected to train their auditors for the change of requirements, MDSAP procedures, and forms. The change of them is going to be notified through transmittal during Q2 2021.


MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM