Third Party Certification System in Japan
-Selection and Supervision of Registered Certification Bodies-

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Office of Standards and Compliance for Medical Devices

Division of Registered Certification Body Assessment

Today’s Agenda

- ☐ Overview of the third-party certification system
- ☐ Assessment system of Registered Certification Bodies (RCBs)
- ☐ Quality Maintenance of RCBs

Background of introduction of the third-party certification system [1]

In 2000, before introduction of the third-party certification system, any medical device to be manufactured had to undergo review and assessment for quality, efficacy, and safety by the Ministry of Health, Labour and Welfare (MHLW) and be approved by the MHLW in view of public health.

Background of introduction of the third-party certification system [2] (problems)

- The paperwork involved in a process from the application to approval often took about 1 year on average, and thus it tended to take longer to market the medical device in Japan than in Europe and the US in 2000.

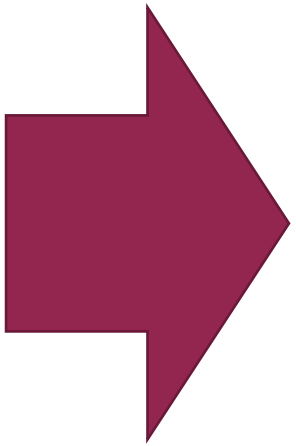
- Foreign manufacturing sites were deemed to have difficulties in responding to the problem, if any, promptly.

✓ From a viewpoint of ensuring the international harmonization, the need for further fulfilled safety measures according to characteristics of the medical device or *in vitro* diagnostics was raised.

Background of introduction of the third-party certification system [3] (points to be modified)

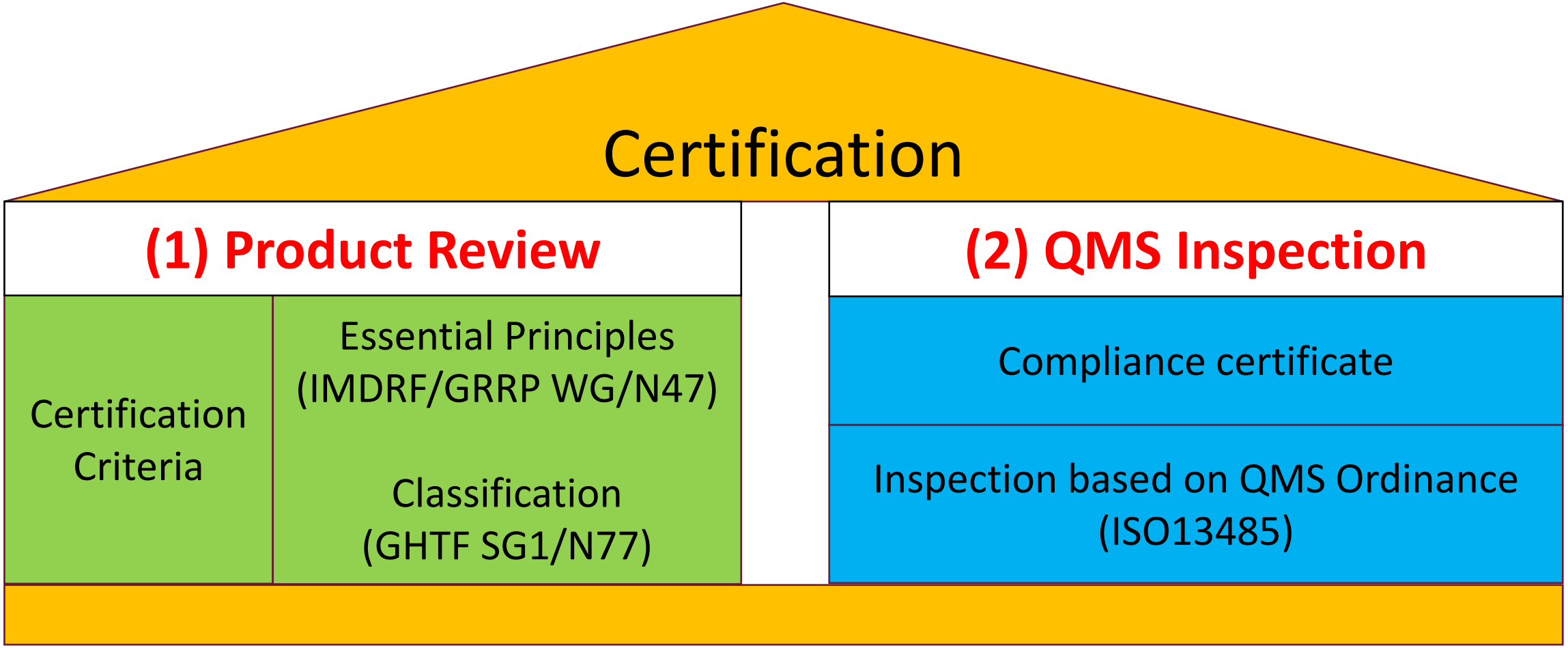
✓From a viewpoint of ensuring the international harmonization, the need for further fulfilled safety measures according to characteristics of the medical device or *in vitro* diagnostics was raised.

Before introduction of the third-party certification system, any medical device to be manufactured had to undergo review and assessment for quality, efficacy, and safety by the MHLW and be approved by the MHLW in view of public health.



- Introduction of medical device classification system according to the risk based on Global Harmonization Task Force (GHTF) classification rules
- Introduction of the third-party certification system for low-risk medical devices and *in vitro* diagnostics in place of the approval system by the MHLW
- The review process includes not only document-based inspection for quality, efficacy, and safety but also on-site inspection at the manufacturing site where necessary.

Certification Structure



Classification of Medical Devices

GHTF Classification		Classification in Japan			
Class	Risk level	**Class**	**Category**	**Pre-market regulation**	**# of JMDN****
A	**Low** Surgical retractors/ tongues depressors	**I**	General MDs	Self declaration	**1,211**
B	**Low to Moderate** Hypodermic needles/ suction equipment	**II**	Controlled MDs + Designated Controlled MDs	**Third-party Certification (Review by RCB*) (Designated Controlled MDs and Designated Specially Controlled MDs)**	**2,003 (1,518 for 3rd Party)**
C	**Moderate to High** Lung ventilator/ bone fixation plate	**III**	Specially Controlled MDs + Designated Specially Controlled MDs	Ministerial Approval (Review by PMDA) (Controlled MDs and Specially Controlled MDs)	**810 (43 for 3rd Party)**
D	**High** Heart valves / implantable defibrillator	**IV**			**370**

*RCB: Registered Certification Bodies **JMDN: Japanese Medical Device Nomenclature

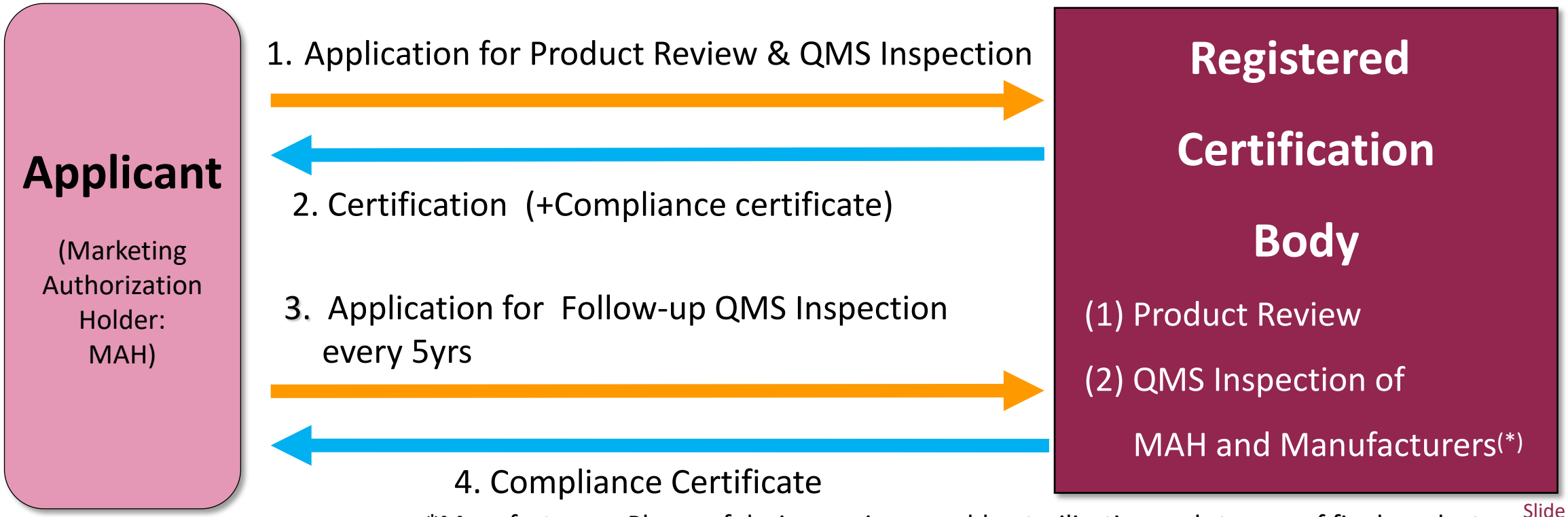
As of March, 2021

Classification of *In Vitro* Diagnostics

GHTF		Classification in Japan			
				Pre-market regulation	
Class	Risk level	Diagnostic infor-mation risk	Category	Products conforming to the notified standards	Novel /Radioactive/ Non-conforming or products with no notified standards
A	Low	Low	**Class I** GOT, GPT, Glucose, LDH, HbA1c, Estradiol, Cholesterol	**Submission of Notification to PMDA** Self-certification Criteria	**Minister's Approval (Review by PMDA)**
B	Low to Mode-rate		**Class II** Blood morphology test, Auto-antibody tests	**Third-party Certification** Certification Criteria	
C	Mode-rate to High	High	**Class III** HIV, HCV, Tumor markers, Micro-biology test	**Minister's Approval (Review by PMDA)** Approval Criteria	
D	High				

Certification Process

Most of Class II medical devices and *in vitro* diagnostics need to be certified by Registered Certification Bodies (RCBs) before their marketing, that is, they are certified without PMDA's review and MHLW's approval.



*Manufacturers: Places of design, main assembly, sterilization and storage of final products

(1) Product Review

Certification Criteria

(Japan-specific requirements)

- Japanese MD nomenclature
- Intended use and indication
- Publicly notified JIS (Class II medical devices)
- Director-General notification (Class III medical devices, some Class II devices, Class II *in vitro* diagnostics)

Essential Principles

- Consistent (harmonized) with IMDRF/GRRP WG/N47: Essential Principles of Safety and Performance of Medical Devices

(2) QMS Inspection

- QMS Inspection is performed based on the QMS requirements harmonized with ISO 13485.
- QMS Inspection is conducted on-site or document-based inspection.
- A QMS compliance certificate is issued after successful inspection.
- The QMS compliance certificate shall be renewed every 5 years.

Today’s Agenda

- ☐ Overview of the third-party certification system
- ☐ Assessment system of Registered Certification Bodies (RCBs)
- ☐ Quality Maintenance of RCBs

Quality requirements for fair and impartial third-party certification bodies

- Allocation of personnel with expertise and experience satisfying requirements for certifying operation
- Possession of facilities, procedures, protocols, and financial base to ensure proper and solid implementation of certifying operation
- Conformity to certain standards eliminating a possibility of unfair certifying operation

Criteria for registration of certification bodies and conditions for rejecting registration

Criteria for registration

1. Any applicant shall conform to both standards below defined by the International Organization for Standardization (ISO) or International Electrotechnical Committee (IEC). (conformity to international standards)
   [1] Requirements for bodies certifying products, processes and services. (ISO/IEC 17065)
   [2] Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021-1)
2. Any applicant for registration shall not be controlled by marketing authorization holders, manufacturers, or foreign manufacturers.

(independence)

(Article 23-7, Paragraph 1 of the Pharmaceutical and Medical Device Act)

Conditions for rejecting registration

The applicant for registration that meets any of the following conditions shall not be registered irrespective of conformity status to the criteria in the above 1 or 2. (non-applicability to disqualification clauses)

[1] A person who has been sentenced to imprisonment owing to violation of the Pharmaceutical and Medical Device Act and for whom two years have not elapsed since the date of either the completion of, or the conclusion of being subject to, the execution of the sentence

[2] A person whose registration has been rescinded and for whom two years have not elapsed since the day of the rescission

[3] A juridical person any of whose executive officers falls under either of the two preceding items

(Article 23-7, Paragraph 2 of the Pharmaceutical and Medical Device Act)

The registration process to be an RCB

2. Document review
6. Document review & decision on whether to register the applicant

MHLW

3. Request for assessment

PMDA

5. Report of assessment results

4. Implementation of assessment
- The Pharmaceutical and Medical Device Act
- ISO/IEC 17021-1: 2015
- ISO/IEC 17065: 2012

1. Application

Certification Body

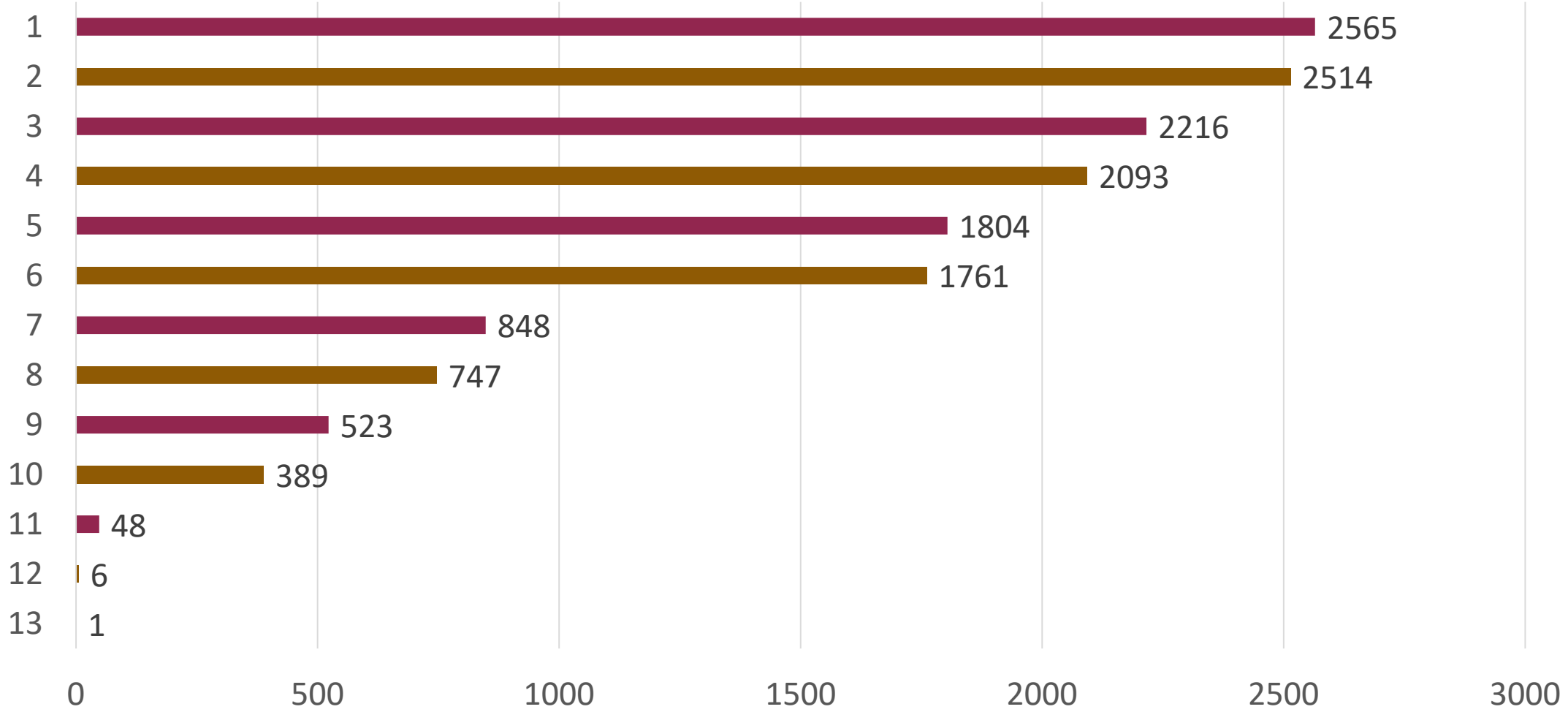
Registered Certification Bodies

Registration no.	Name of the RCB	Medical Devices	IVDs
AA	TÜV SÜD Japan	Yes	Yes
AB	TÜV Rheinland Japan	Yes	Yes
AC	DQS Japan	Yes	Yes
AD	BSI Group Japan	Yes	Yes
AF	SGS Japan	Yes	Yes
AG	Cosmos Corporation	Yes	No
AH	Japan Quality Assurance Organization (JQA)	Yes	Yes
AI	Nanotec Spindler Corporation	Yes	Yes
AK	Japan Electrical Safety & Environment Technology Laboratories (JET)	Yes	No
AL	Japan Association for the Advancement of Medical Equipment (JAAME)	Yes	Yes
AM	AiCS Inc.	Yes	No
AO	DEKRA Certification Japan*	Yes	No

*Abolished in the end of March, 2021

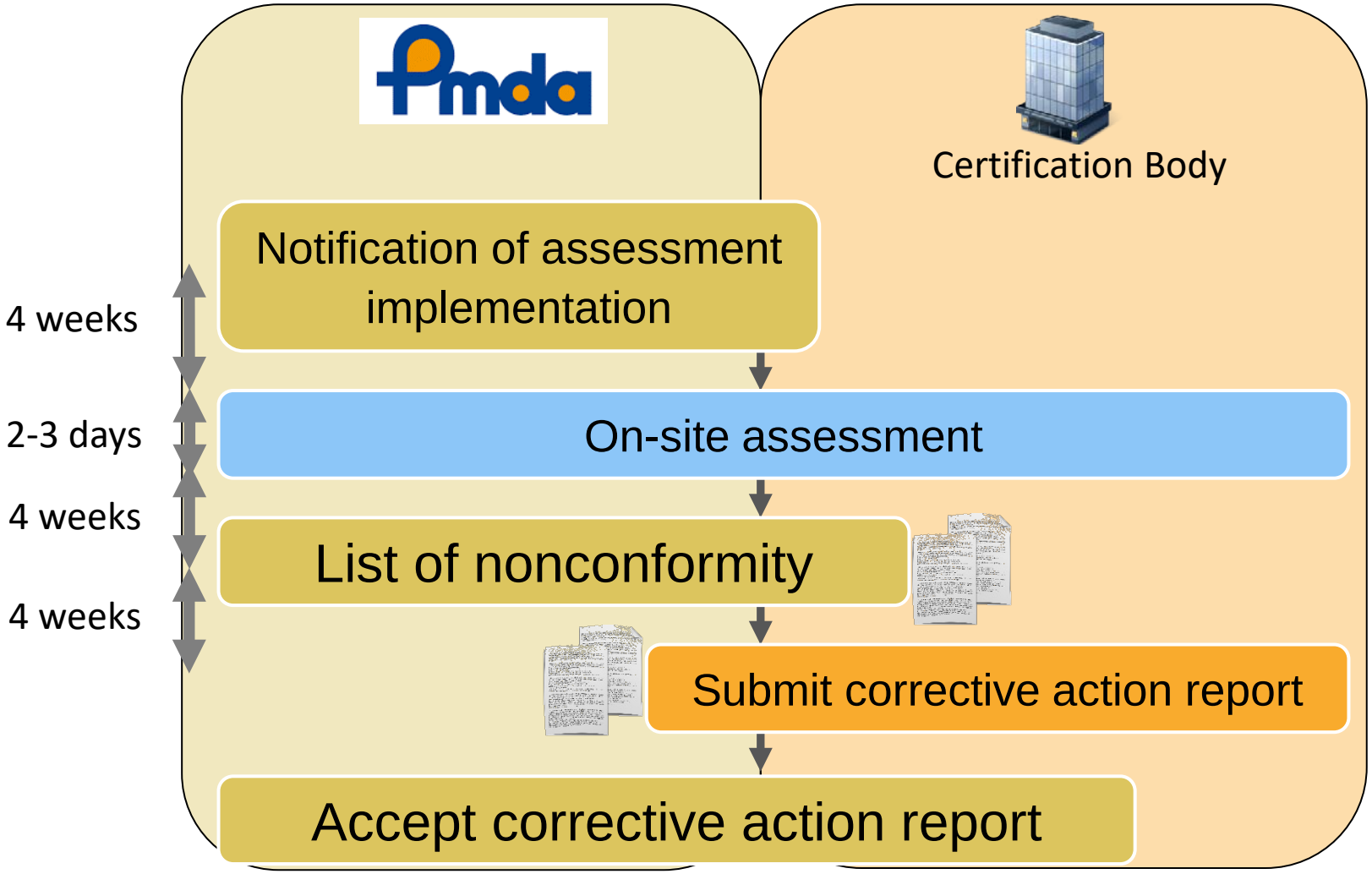
As of March, 2021

Number of Certifications



As of March, 2021

On-site Assessment Activities Flow



Surveillance Assessment

4. Check of assessment results

MHLW

1. Request for assessment

PMDA

3. Report of assessment results

2. Implementation of assessment
- The Pharmaceutical and Medical Device Act
- ISO/IEC 17021-1: 2015
- ISO/IEC 17065: 2012

5. Notification of assessment results

RCB

Re-recognition Assessment

2. Document review
6. Document review & decision on whether to register the applicant

MHLW

3. Request for assessment

PMDA

Pharmaceuticals and Medical Devices Agency

5. Report of assessment results

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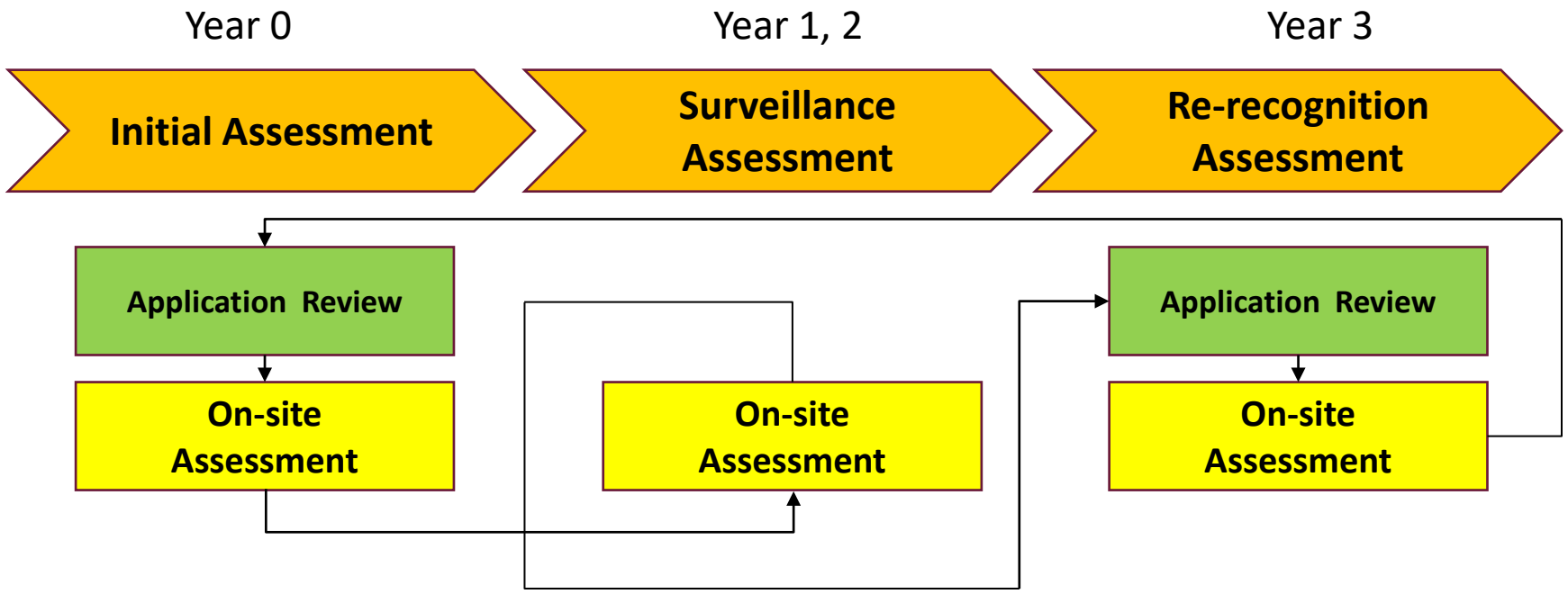
1. Application

Certification Body

Assessment Activities



Assessment checkpoints

1. Conformity with PMD Act, ISO/IEC 17021-1 and ISO/IEC 17065
2. Sampling of certified products

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Efforts to maintain Quality of RCBs

- Training
  - ✓Certification criteria of Class III medical devices
  - ✓Issues frequently found in assessment by MHLW/PMDA
- Inquiry system
  - ✓Applicability to evaluation for certification
  - ✓Questions related to QMS inspection
  - ✓The answers to the inquiries are available on PMDA website for sharing.
- Tripartite consultation
  - ✓The regulatory authority, RCBs and marketing authorization holder (MAH) participate and discuss various items.

Training for registered certification bodies

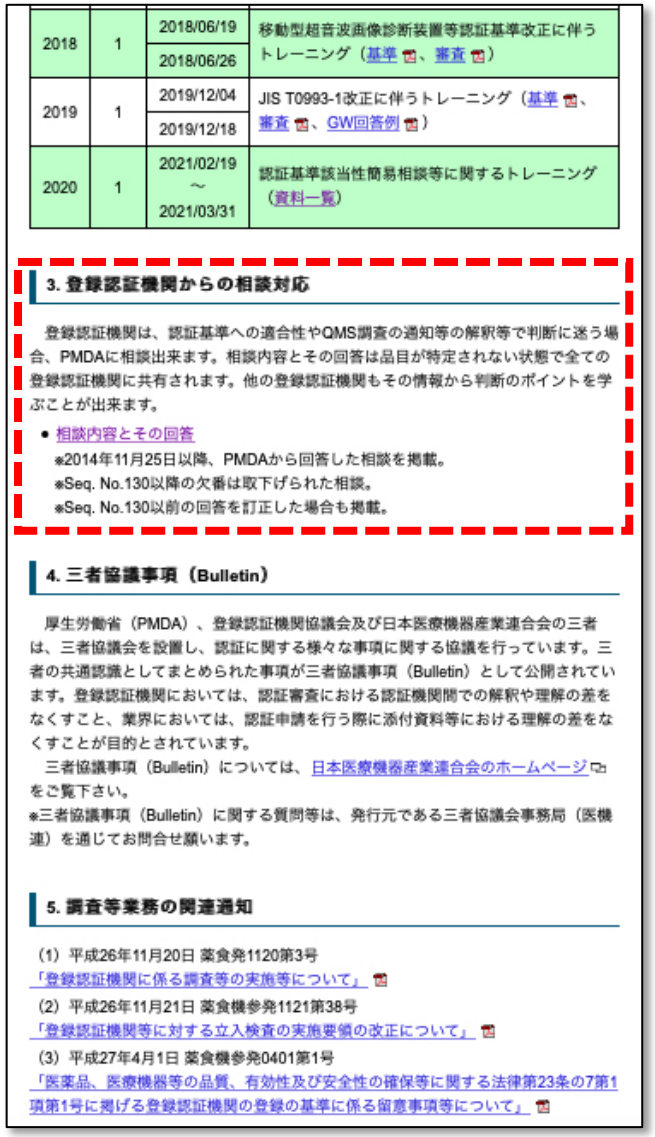
- ✓PMDA provides training to reviewers of RCBs so that they can improve their ability to conduct product certification reviews and conformance.
- ✓Training is opened to all RCBs and planned every year.
- ✓Training materials are available on PMDA website for sharing.

https://www.pmda.go.jp/review-services/reexamine-reevaluate/registered-cb/0001.html

Answer to inquiry from RCBs

- ✓ RCBs can consult PMDA about conformance status to the certification criteria and interpretation of notification for QMS inspection.

- ✓ Consultation content and its result are available on PMDA website for sharing so that the other RCBs can also learn the judgement.



2018	1	2018/06/19 2018/06/26	移動型超音波画像診断装置等認証基準改正に伴うトレーニング（基準、審査）
2019	1	2019/12/04 2019/12/18	JIS T0993-1改正に伴うトレーニング（基準、審査、GW回答例）
2020	1	2021/02/19 ～ 2021/03/31	認証基準該当性簡易相談等に関するトレーニング（資料一覧）

3. 登録認証機関からの相談対応

登録認証機関は、認証基準への適合性やQMS調査の通知等の解釈等で判断に迷う場合、PMDAに相談出来ます。相談内容とその回答は品目が特定されない状態で全ての登録認証機関に共有されます。他の登録認証機関もその情報から判断のポイントを学ぶことが出来ます。

- 相談内容とその回答
  - ※2014年11月25日以降、PMDAから回答した相談を掲載。
  - ※Seq. No.130以降の欠番は取下げられた相談。
  - ※Seq. No.130以前の回答を訂正した場合も掲載。

4. 三者協議事項（Bulletin）

厚生労働省（PMDA）、登録認証機関協議会及び日本医療機器産業連合会の三者は、三者協議会を設置し、認証に関する様々な事項に関する協議を行っています。三者の共通認識としてまとめられた事項が三者協議事項（Bulletin）として公開されています。登録認証機関においては、認証審査における認証機関間での解釈や理解の差をなくすこと、業界においては、認証申請を行う際に添付資料等における理解の差をなくすことが目的とされています。

三者協議事項（Bulletin）については、日本医療機器産業連合会のホームページをご覧下さい。

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5. 調査等業務の関連通知

（1）平成26年11月20日 薬食発1120第3号
「登録認証機関に係る調査等の実施等について」

（2）平成26年11月21日 薬食機参発1121第38号
「登録認証機関等に対する立入検査の実施要領の改正について」

（3）平成27年4月1日 薬食機参発0401第1号
「医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第23条の7第1項第1号に掲げる登録認証機関の登録の基準に係る留意事項等について」

様式1

令和元年 11 月 15 日　　No.19-AG06[1]

認証基準への適合性等の判断確認

質問認証機関（ 株式会社コスモス・コーポレイション ）

担当者名及び連絡先メール（　　）

【質問】

照会の概要	ワイヤレス給電を用いた電子式診断用スパイロメータの認証基準への適合性及び認証審査における取扱いについて
該当する認証基準名	・認証基準：別表 3-605　電子式診断用スパイロメータ基準 ・一般的名称：電子式診断用スパイロメータ 定義：肺疾患の診断又は検診のため、肺の空気量及び気流速度を測定する電動式装置をいう。これらの測定値から患者の肺機能に関する情報が得られ、正常値又は以前の値と比較することができる。 ・使用目的又は効果：肺の空気量及び気流の速度を測定すること。
製品の概略	・ハンディタイプの電子式診断用スパイロメータであり、使用目的や測定の原理などは、既存のスパイロメータと何ら変わらない。 ・当該製品は、バッテリ（充電池）によって作動するが、充電池は製品本体に内蔵されており、充電池への給電は、ワイヤレス給電によって行われる。 ・給電用の充電器は、ワイヤレス給電の規格（Qi 規格）に基づいており、汎用として流通しているものを用いる。 ・給電中（充電中）に製品は、作動しない構造である。
適合性の判断が必要な箇所（論点）	① ワイヤレス給電を用いた医療機器の既存品は見当たらないが、この給電方法がただし書きに該当するか否か。 ② ワイヤレス給電用の充電器は、バッテリ充電には欠かせない構成品ではあるが、JIS T 0601-1 又は他の電気安全性規格への適合性の確認が必要であるか。
認証機関の判断素案	① ワイヤレス給電については、ただし書き（新規性）に該当しない。 ② ワイヤレス給電用の充電器は汎用品として流通されているものであるため、認証審査において更なる評価は必要ない。ただし、充電時のスパイロメータの安全性（例えば温度上昇等）については、JIS T 0601-1 に従って評価されていることを確認する必要がある。
判断素案の根拠	① ワイヤレス給電は、すでに一般消費者がスマートフォンなどで幅広く使用している実態から、ただし書き（新規性）には該当しない。 ② ワイヤレス給電用の充電器は充電にしか用いることができない（充電中にはスパイロメータ作動しない）ため、適否照会 15-AD02 の回答（再修正日：平成 30 年 8 月 28 日）“その他メモ”の 1. と同様の扱いとすることが妥当である。

PMDA 記入欄

回答日　令和元年11月21日

[1] No.は、「No.09-A○xx」のように付与してください。
15：西暦下2ケタ、A○：登録番号、xx：各機関で付与した追い番

回答担当者（医療機器調査・基準部　登録認証機関監督課）

【回答】

結論	認証基準に対する適合性　（　条件付き有　・　無　）
判断の根拠	① 給電方法の差異が製品の安全性及び性能に影響せず、適切な既存品目と実質的に同等であると判断できる場合には、認証基準に適合するものと判断して差し支えない。 ② 以下の条件を満たす場合、ワイヤレス給電用の充電器は、ME システムの範囲外であり、当該充電器の電気的安全性は JIS T 0601-1 に基づく評価を要しない。 1）当該相談品であるスパイロメータが給電中作動しないこと。 2）スパイロメータとして使用中に、スパイロメータ本体が充電器と機能接続しないこと。
その他メモ	・認証申請書の形状、構造及び原理欄に充電システムの原理を記載させること。 ・認証申請書の使用方法欄に、併用可能な充電器の条件を記載させること。

以上

Procedures for responding to consultation:
Response will be made after confirmation of the relevant division of MHLW on results from discussion between the supervising division, standard division, and reviewing office of PMDA.

Target period to response: 30 days

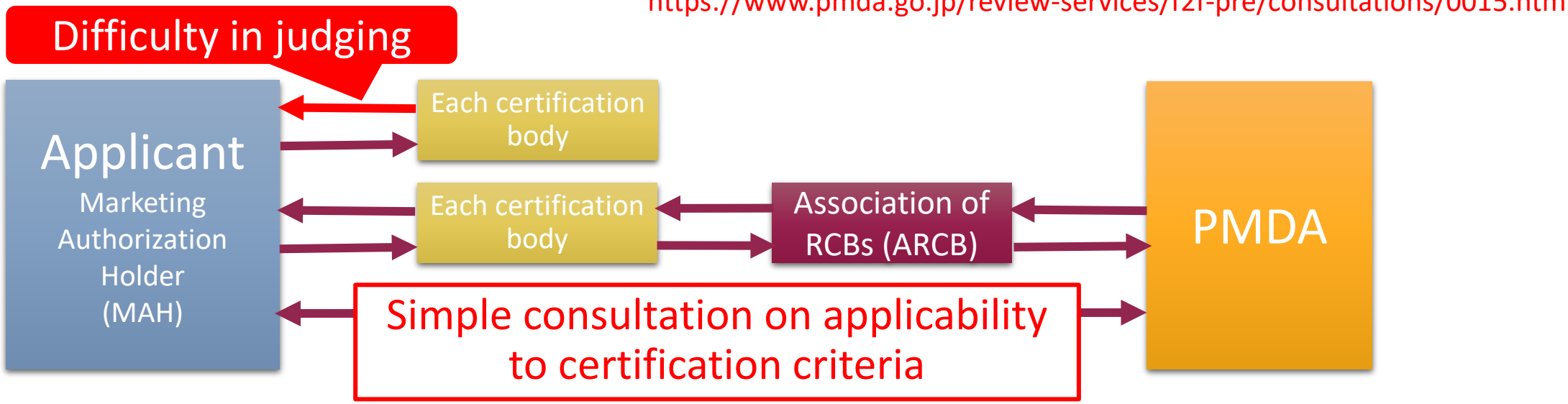
Simple consultation on applicability to certification criteria
(except for cases where non-conformance to certification has been confirmed)

Request from Applicant (MAH)

RCBs inform PMDA of difficulty in judging applicability to the certification criteria. Inquiries can be accepted through the association of RCBs, but it sometimes takes a long time. Early clarification is desired to shorten the time to application.

⇒ Service of simple consultation on applicability to certification criteria was started on April 1, 2019.

https://www.pmda.go.jp/review-services/f2f-pre/consultations/0015.html



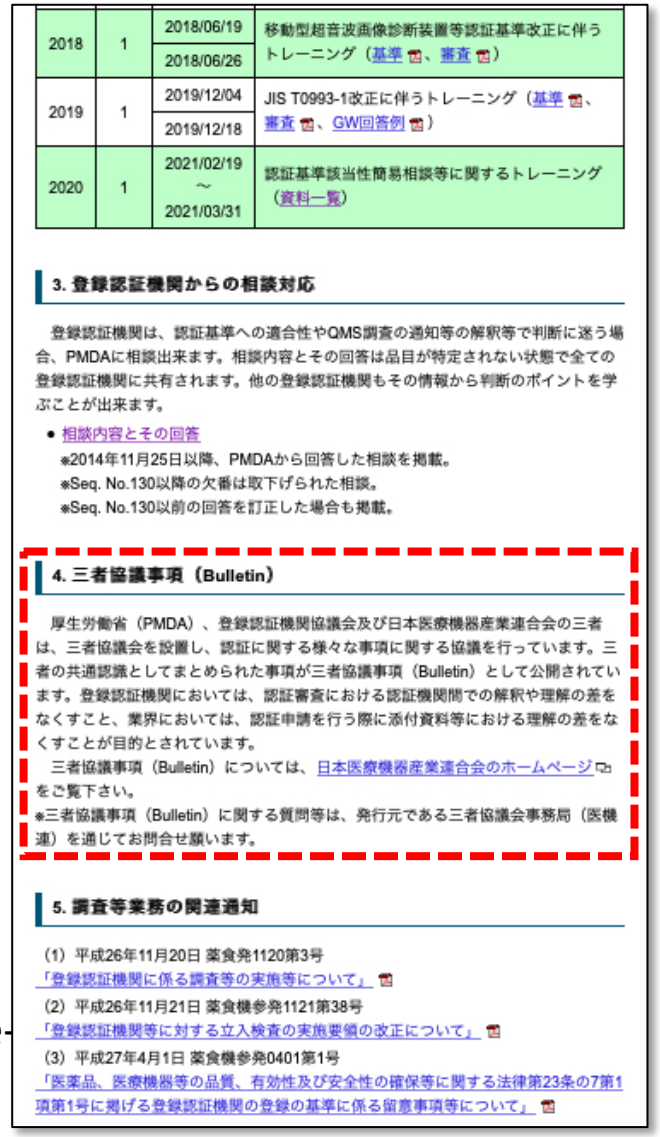
* The simple consultation service will handle only cases where certification bodies have claimed difficulty in judging applicability to the certification criteria.

Note) If non-applicability to the certification criteria is judged, PMDA will accept consultation through the existing service (consultation about protocols for “Performance,” “Quality,” “Safety” and evaluation).

Tripartite consultation items (Bulletin)

- ✓Three parties consisting of the regulatory authority (i.e. MHLW/PMDA), the registered certification body association and Japan Federation of Medical Devices Associations (JFMDA) have organized the tripartite consultation committee to discuss various items related to certification.
- ✓Items recognized in tripartite consultation are disclosed as Bulletin on JFMDA website.
- ✓Tripartite consultation gives better interpretation and understanding for the regulatory process of review and inspection for certification.

https://www.pmda.go.jp/review-services/reexamine-reevaluate/registered-cb/0001.html



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「登録認証機関等に対する立入検査の実施要領の改正について」
（3）平成27年4月1日 薬食機参発0401第1号
「医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第23条の7第1項第1号に掲げる登録認証機関の登録の基準に係る留意事項等について」

If a MAH has a doubt about review for certification

If a MAH has a doubt about the RCB's judgment, interpretation, or request in a review of a product item or QMS inspection, ask the RCB to present the rationale.

If a MAH have any comment, for instance, a MAH is not convinced by the RCB's explanation, MAH has a rationale against it, or MAH cannot accept it, present "Complaint" or "Objection" to the certification body in writing to seek specific actions.

If a satisfactory solution is not obtained, provide the information to the "Contact office for information related to the third-party certification system" on the JFMDA's website established by the tripartite consultation committee.

The tripartite consultation committee consisting of the regulatory authority, the registered certification body association, and industry will strive to solve the problem.

Take-home message

- To ensure that medical devices with “improved safety” and “improved efficacy” are marketed as “promptly” as possible, efficient measures to review and assess the quality, efficacy, and safety of medical devices according to the risk should be considered.

- Effective actions to put the third-party certification system in operation smoothly
  - ✓ Training of reviewers
  - ✓ Action in response to consultation from certification bodies
  - ✓ Tripartite consultation consisting of the regulatory authority, the registered certification body association and the industry association

    (including marketing authorization holder)

Thank you!