Outline of the medical device program and its correspondence

JFMDA
The Japan Federation of Medical Devices Associations

July 3, 2018

Hiroshi Furukawa(Canon Medical Systems Corporation)

The Japan Federation of Medical Devices Associations
Group Leader of Medical Device Program WG, Regulatory System Committee

Japan Medical Imaging and Radiological Systems Industries Association
Vice-Chairman of Regulation and Safety Division

Outline of the Presentation

1. Even an Independent Program To Be Regarded as a Medical Device after the Regulatory Revision
2. Applicability to the Medical Device Program
3. Generic Names for the Medical Device Program
4. Procedures for Medical Device Program Sales
5. Matters To Be Considered Regarding the Use Environment
6. Software Used in the Healthcare Field
7. GHS Development Guidelines
8. Procedures for Compliance Declaration

Reference
- A: Basic concept on the applicability of radiotherapy-related programs to medical devices
- B: Additional Generic Names for the Medical Device Program
- C: The Number of Medical Device Programs Approved/Certified
- D: The Status of GHS Mark Registered Products

1. Even an Independent Program To Be Regarded as a Medical Device after the Regulatory Revision

- Programs that demonstrate their performance as medical devices by being installed on IT equipment such as general-purpose PCs
- Independent programs and recording media that contain them are also subject to the regulations.

Examples of expected independent programs

It will become possible to use the program by installing it on a medical device that uses a general-purpose PC.

Software for conventional diagnostic imaging device workstations (data processing for X-ray/MRI equipment, etc.)

Diagnostic imaging software on smartphones or tablets

Before the revision (up to Nov. 24, 2014)

Software segment (Program)

Hardware segment

A software segment alone is not subject to medical device regulations; such segment is subject to the regulations when it has been incorporated in the hardware segment.

After the revision (Nov. 25, 2014 onward)

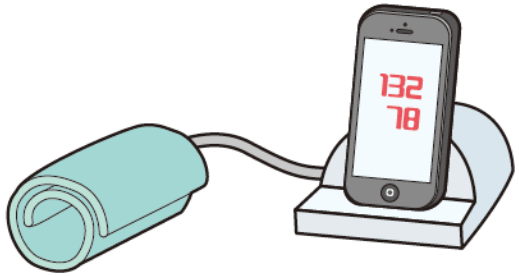
Software segment (Program)

<u>Independent program regarded as a medical device</u>

* Already positioned as a medical device In Europe and the United States.

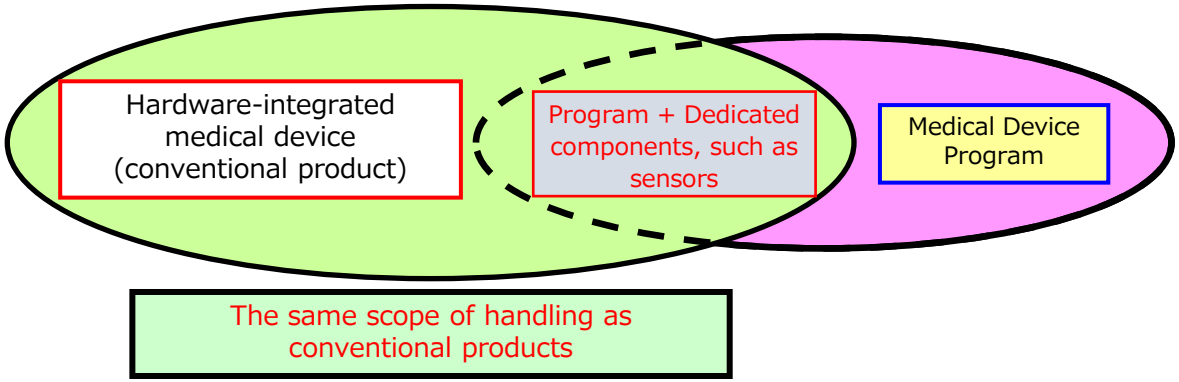
1-1 For the Clarification of the Scope of the Medical Device Program (1)

How should we handle programs designed to be installed on IT equipment (general-purpose IT products, such as PCs and mobile terminals) to, for example, collect data directly from the human body by controlling sensors, etc.?



⇨ We should handle such programs as with existing medical devices, in a lineup including general-purpose products! (Programs are handled in the scope of machines/instruments, as their components)

Schematic Image of the Scope of the Medical Device Program



The following needs to be put in order.

- Make it possible to identify general-purpose products (trade name, OS version, etc.) so that they do not have to be shipped from manufacturing/distribution business license holders alone.
- Make it possible to download the dedicated software from a specific site.

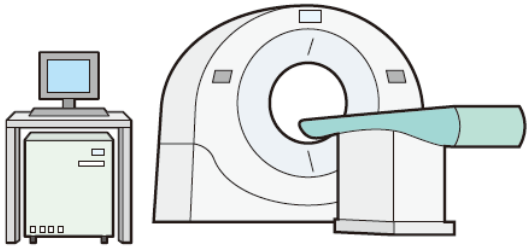
1-2 For the Clarification of the Scope of the Medical Device Program (2)

- How should we handle programs included in existing electric medical devices?

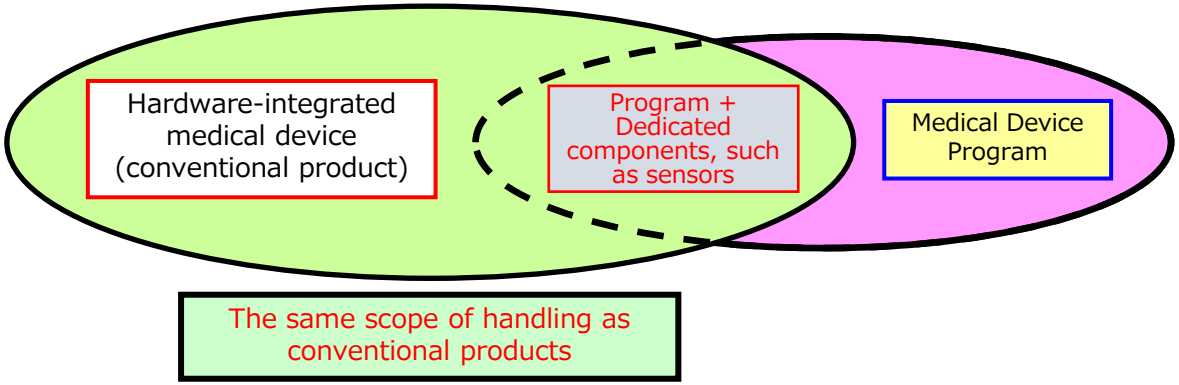
  ⇨ Handling of medical device components (They do not apply to the Medical Device Program.)

- How should we handle programs, etc. designed to control medical devices by being connected to them directly or via a network, such as the Internet?

  ⇨ We should handle them as with existing medical devices, in a lineup including general-purpose products! (Programs are handled in the scope of machines//instruments, as their components)



Schematic Image of the Scope of the Medical Device Program



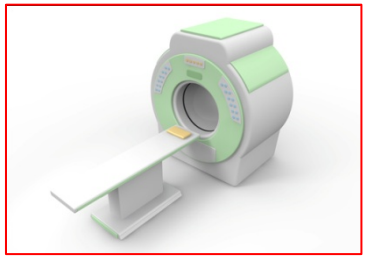
1-3 How about the Functions of Machines/Instruments and Programs as Part of Medical Devices?

Medical device (machines/instruments)
Collects information from patients for diagnoses, etc. to provide it to medical practice.

Medical device (program)
Further processes data collected by other medical devices to provide it to medical practice.

Medical practice

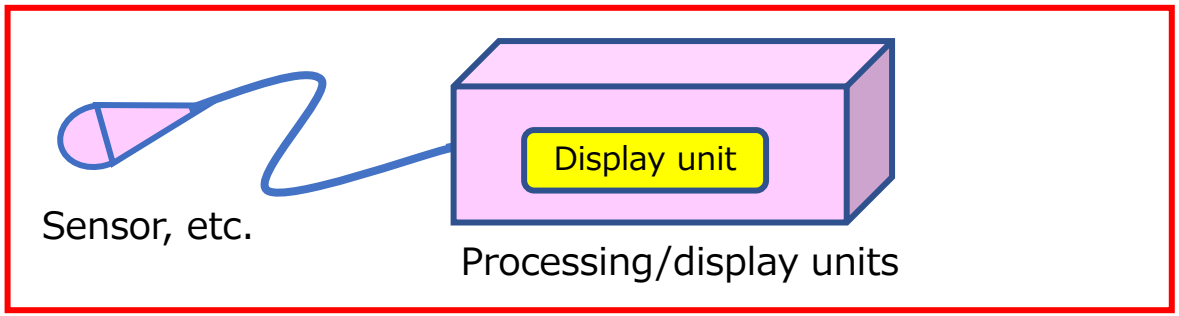
Data collection/ processing



Data processing

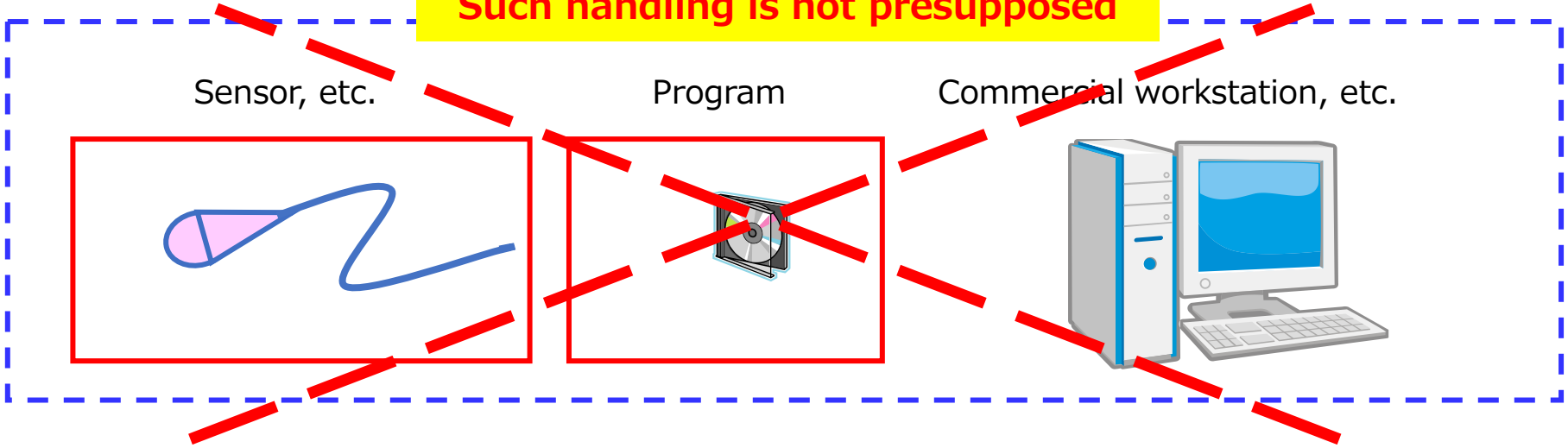
1-4 Handling of a Medical Device as Divided Components is Not Presupposed

Conventional medical device



It is not intended to divide a medical device and combine its components with commercial products on site to assemble them as the original medical device.

Such handling is not presupposed



2. Applicability of the Program to Medical Devices

The target is programs to be used for the diagnosis, treatment, or prevention of diseases; after having being subjected to public comments (Sept. 29 to Oct. 13), specific examples were publicized through "The Basic concept on the applicability of the program to medical devices" (PFSB/CND Notification No. 1114-5, dated November 14, 2014).

When determining the applicability of programmed medical devices, the following two points should be considered, based on their characteristics as intangibles, and taking into account their impacts on human life, health, and functions.

(1) In view of the importance of results obtained from programmed medical devices, how much do they contribute to the treatment, diagnosis, etc. of diseases?

(2) When programmed medical devices have developed functional disorders, how much probability of overall risks (risks when the devices have failed) could be expected, including risks of affecting human life and health?

2-1 Programs Applicable to Medical Devices

1) Programs with which to process/treat data (including images) obtained from medical devices, for the purpose of preparing indicators, images, graphs to be used for diagnosis or treatment

④ Programs with which to process data of temporal changes in concentrations of contrast media and radiopharmaceuticals on images captured using nuclear medicine diagnosis devices with contrast media for the purpose of calculating physiological parameters (tissue blood flow volume, load responsiveness, substrate metabolic rate, receptor binding capacity, etc.) to perform a statistical comparison with healthy subject groups, etc.

2) Programs (including simulations) with which to help decide treatment plans/methods

① Programs with which to process/treat image data obtained from diagnostic imaging devices, such as CT, to present and evaluate/diagnose candidates for treatment methods, through displaying conceptual images of the position of teeth or implants, operative simulations of orthodontics or implant treatment, for the purpose of preparing treatment plans and predicting expected outcomes of such treatment

2-2 Programs Not Applicable to Medical Devices

1) Programs with which to transfer, store, and display data obtained from medical devices to use them as medical records

① Programs with which to transfer data obtained from medical devices to other programs, etc., without processing them using methods other than lossless compression (data transfer programs without data display function)

2) Programs with which to process/treat data (excluding images) (excluding those used for diagnosis)

① Programs with which to read data obtained from medical devices and then stored on recording media for the purpose of displaying them on general-purpose computers, etc. (e.g., programs with which to read data obtained from a continuous positive airway pressure (CPAP) therapy device, recorded on an SD card, etc., to be used for the home treatment of sleep apnea syndrome (apnea/hypopnea index, supply pressure, operating time, etc.), using a general-purpose computer, etc. for the purpose of preparing/displaying tables, etc. of such data)

3) Educational programs

4) Programs designed for explanations to patients

5) Programs for maintenance

6) Programs for supporting hospital tasks

7) Programs health management

② Programs with which to transfer data obtained from medical devices, such as an electronic manometer, to display, store, and chart such data for personal recording/management purposes

8) Programs equivalent to general medical devices (highly unlikely to affect human life and health even in the case of functional disorders, etc.)

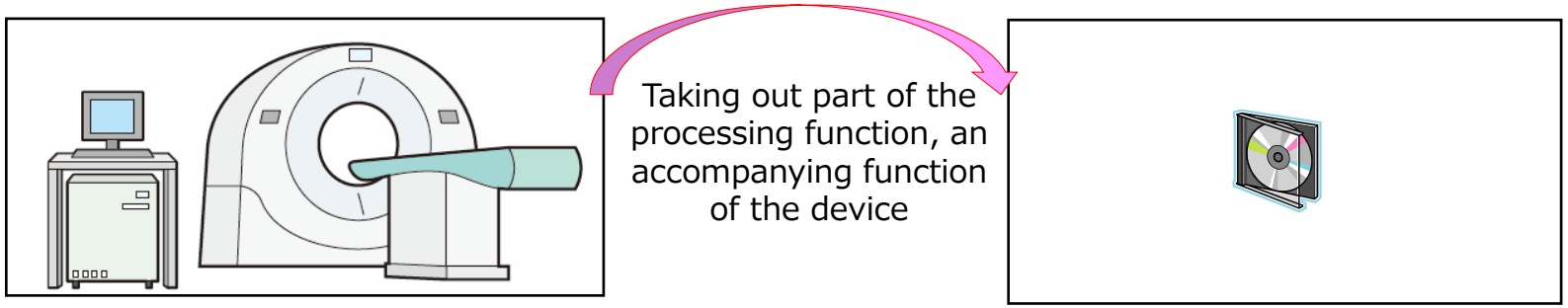
① Programs with which to perform visual acuity tests and color perception tests using a general-purpose computer, personal digital assistant, etc. (programs that display functions equivalent to an optotype or color perception table of a general-purpose computer)

3-1 Generic Names for the Medical Device Program

When the law was enforced, a total of 150 generic names applicable to the Medical Device Program were designated.

Of the conventional medical devices (machines/instruments) with established certification criteria, these names were selected for the likelihood of part of their processing functions, which accompany the devices, serving as a Medical Device Program on its own, and their certification criteria were also established.

This procedure was implemented in response to the following consideration: While conventional hardware-integrated medical devices should be handled as certified items, unless certification criteria are established, handling an image processing unit, a device's accompanying function, as a Medical Device Program on its own inevitably means handling it as an approved item.



X-ray CT device: Certification

Medical Device Program:
To be handled: Approval => Certification

Medical Device Classes and Pre-marketing Procedures

Classification of medical devices by risk			Pre-marketing procedure	Application category, etc.
Specially controlled medical devices	Class IV	The device is highly invasive and may directly lead to life-threatening risk in the event of malfunction. Examples: Pacemakers, heart valves, and stents	Approval by the Minister	Application for manufacturing/distribution approval • New medical devices • Improved medical devices • Generic medical devices
	Class III	The risk to patients in the event of malfunction is regarded as relatively high. Examples: Dialyzers, artificial bones, and radiotherapy devices		Application for special control certification
Controlled medical devices	Class II	The risk to patients in the event of malfunction is regarded as relatively low. Examples: Diagnostic imaging devices, electronic manometers, electronic endoscopes, and dental alloys	Third-party certification	Application for manufacturing/distribution certification
General medical devices	Class I	The risk to patients in the event of malfunction is regarded as almost negligible. (Example) in vitro diagnostic devices, steel accessories, dental laboratory instruments, X-ray films	(No approval required)	Marketing/distribution declaration

3-2 Generic Names for the Medical Device Program

When the revised law was enforced (November 2014)

A total of 150 names were designated, including programs for general-purpose diagnostic imaging device workstations.

Ref. B_1

At the same time, a total of 108 certification criteria for these names were established.

For the Medical Device Program, the last 19 names were designated.

Ref. B_2

Category	Class III	Class II
Programs for disease diagnosis	1	155
Programs for disease treatment	8	5
Programs for disease prevention	—	—

3-5 Comparison between Devices (Machines/Instruments) and Programs

Category name		Medical device (machines/instruments)	Medical Device Program
Generic names		General-purpose diagnostic imaging device workstations	Program for general-purpose diagnostic imaging device workstations
Definition		These workstations refer to stand-alone general-purpose image processing workstations, designed to be used in combination with diagnostic imaging devices, such as digital X-ray devices, X-ray computerized tomography (CT), fluoroscopic devices, magnetic resonance imaging (MRI) devices, gamma cameras, PET devices, and SPECT devices, regardless of types of hardware and configuration. They may be regarded as one of the components of a PACS device. These workstations differ from operator consoles in that they are usually not equipped with controls with which to directly operate the imaging device. The product is capable of receiving/transferring data both online and offline and generally located in a site away from the operator console. The product is configured in such a manner that it is capable of further processing images and information of the patient collected by each imaging device and providing a function to display them. Applicable products are limited to those with a function to provide information required to determine, evaluate, or diagnose clinical conditions.	These programs constitute general-purpose diagnostic imaging device workstations and regarded as Medical Device Programs that further process information obtained so that it is used in diagnosis, etc. In some cases, recording media that contain such programs are also included.
Certification criteria	**Criteria name**	487: Criteria for Nuclear Medicine Device Workstations, etc.	888: Criteria for Programs, etc. for Nuclear Medicine Device Workstations
	Standards	JIS C6950-1	JIS C6950-1
	Intended use or indications	Processing by computer image data of the human body provided by diagnostic imaging devices, etc., and then providing processed image data to medical practice (excluding workstations equipped with an automatic diagnostic function).	Processing by computer image data of the human body provided by diagnostic imaging devices, etc., and then providing processed image data to medical practice (excluding workstations equipped with an automatic diagnostic function).

4-1 Marketing of the Medical Device Program: Advertising (newly added)

When distributors of medical devices advertise that they provide a Medical Device Program through telecommunication lines, they shall display the matters described below.

(1) The name/trade name of the distributor

(2) Telephone number or other contact information

(3) Other required information

It is required to sell anything to medical institutions as the action of a distributor.

○○ Program
Download Sales

(Advertising)

販売業者　○○株式会社
東京都○○区・・・
TEL　03-××××
E-mail　・・・・・
@・・・.co.jp
その他必要な事項

4-2 Special Provision for Descriptions on the Medical Device Program (newly added)

(1) Regarding recording media containing Medical Device Programs, it is required not only to describe the matters, as specified in each subparagraph (descriptions on the immediate package, etc.) in Paragraph 1, Article 63 of the law, on the recording media concerned or its immediate container or package, but also to provide, along with such Medical Device Program, an electromagnetic record of these matters, recorded in such a manner that it is easy for users of the Medical Device Program to read them.

The description needs to be displayed on both locations.

Legally required description on recording media (on the recording media or its immediate container or package)

Legally required description on the screen
The descriptions must be viewable on the screen.

4-3 Special Provision for Descriptions on the Medical Device Program (newly added)

(2) Regarding Medical Device Programs provided through telecommunication lines, in place of describing the matters, as specified in each subparagraph (descriptions on the immediate package, etc.) in Paragraph 1, Article 63 of the law, it is allowed to provide information on such matters to users of these Medical Device Programs, as listed below.

(A) The distributor of the Medical Device Program provides information on the matters concerned to users of the Medical Device Program before they receive it through telecommunication lines.

(B) The distributor of the Medical Device Program provides users of the Medical Device Program with electromagnetic records of information on the matters concerned, recorded in such a manner that it is easy for such users to read them.

Both descriptions are required

The screen of the distributor

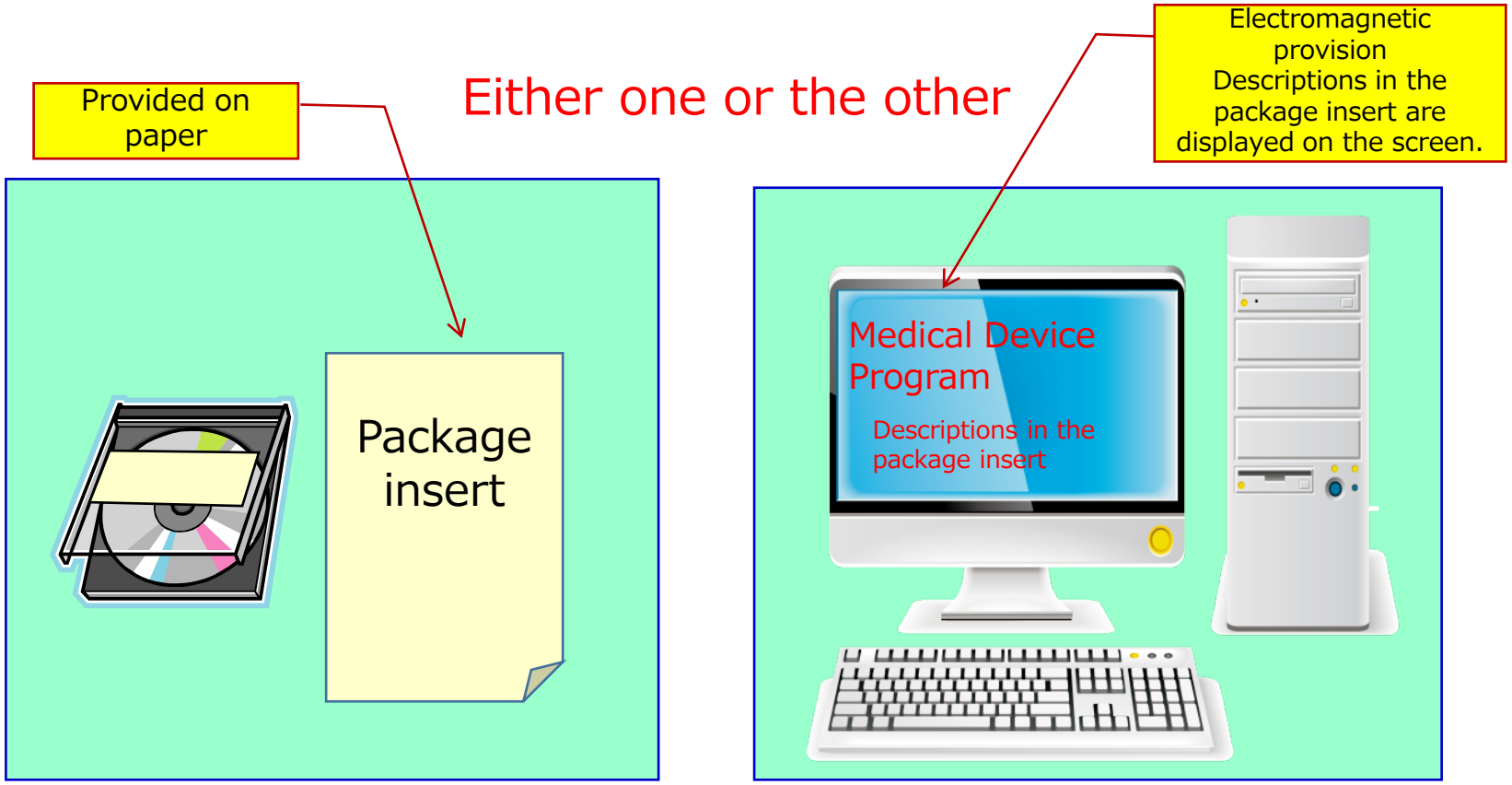
The legally required description needs to be viewable before downloading.

The screen after installation

The legally required description needs to be viewable on the screen.

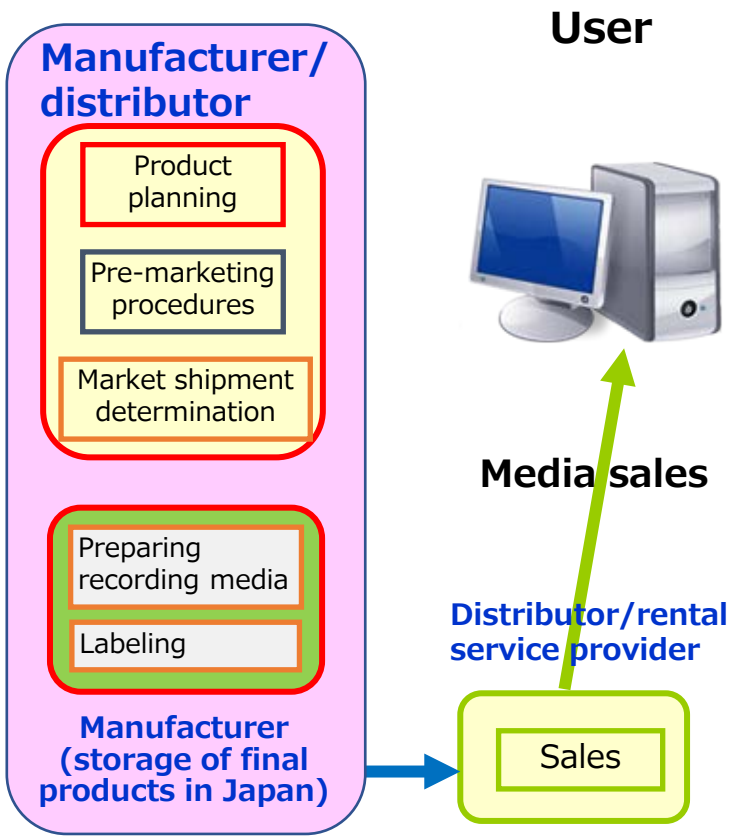
4-4 Special Provision for Descriptions on the Medical Device Program in the Package Insert (newly added)

When the descriptions in the package insert, etc. are incorporated, as an electromagnetic record, in the Medical Device Program, it is not required for the program to describe such matters on itself or its immediate container or package, regardless of the provision in each subparagraph (matters to be described on the immediate package, etc.) in Paragraph 1, Article 63-2 of the law.

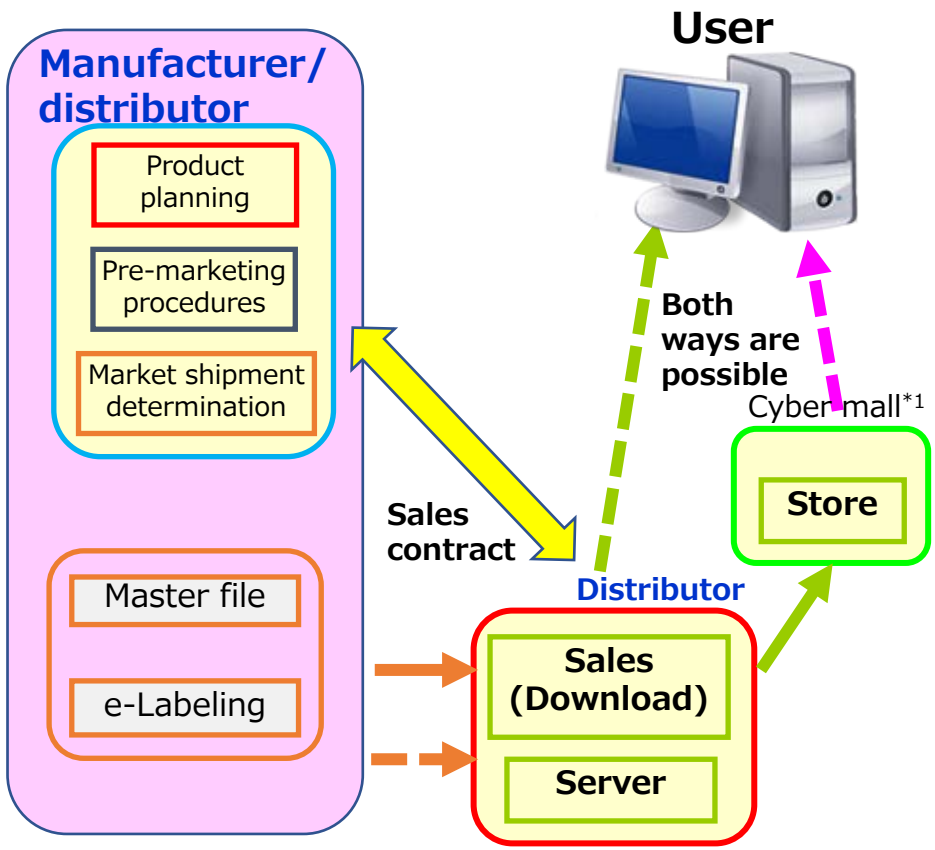


4-5 Medical Device Program Sales

Provision through recording media



Provision through telecommunication lines (Handling of download)

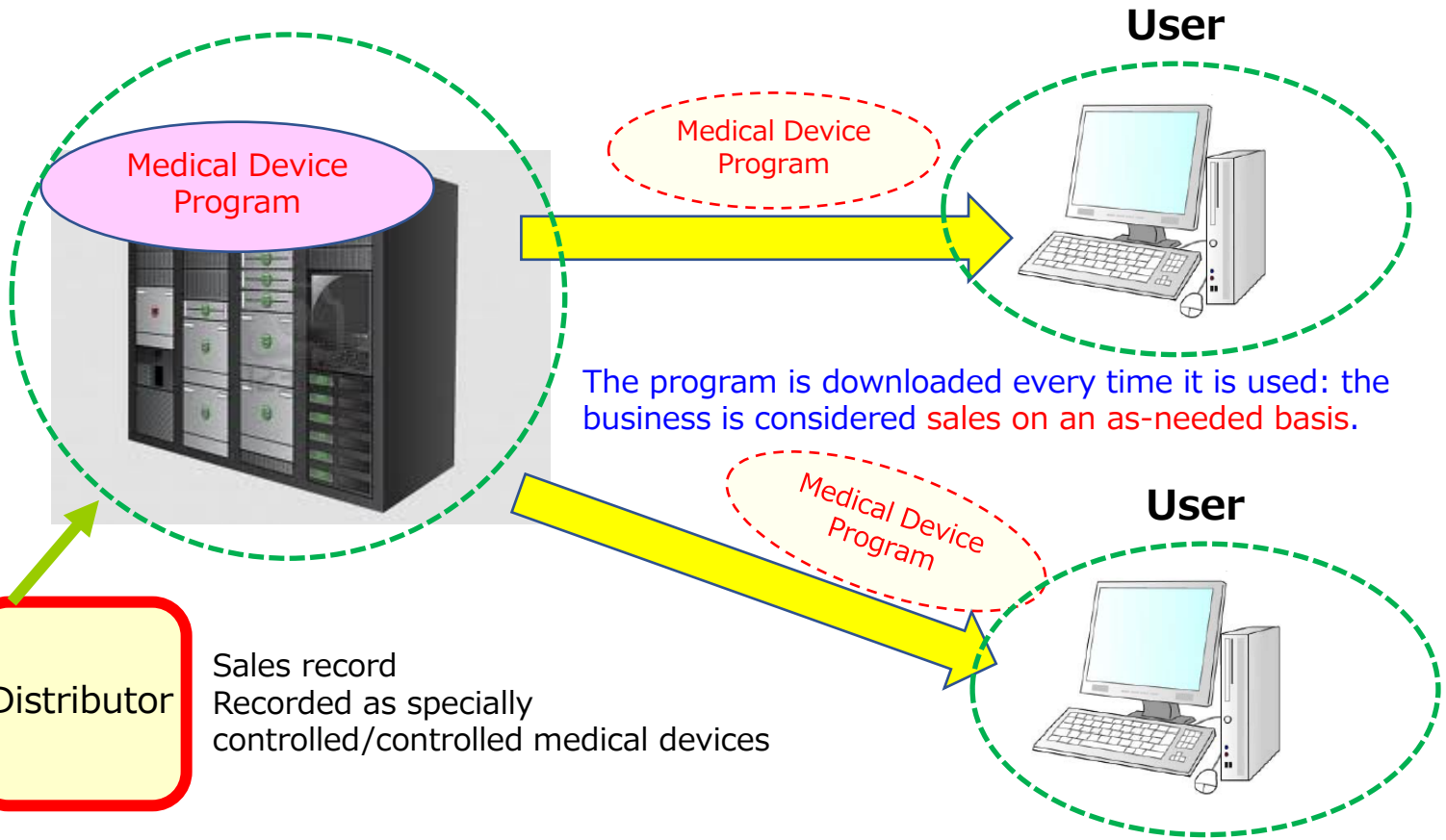


*1: Having the manufacturer take responsibility eliminates the necessity of cyber mall operators, etc. acquiring medical device marketing licenses, etc.

5-1 Matters To Be Considered Regarding the Use Environment (1)

The Medical Device Program is placed on the server, but when the program is used, it is processed by an individual PC.

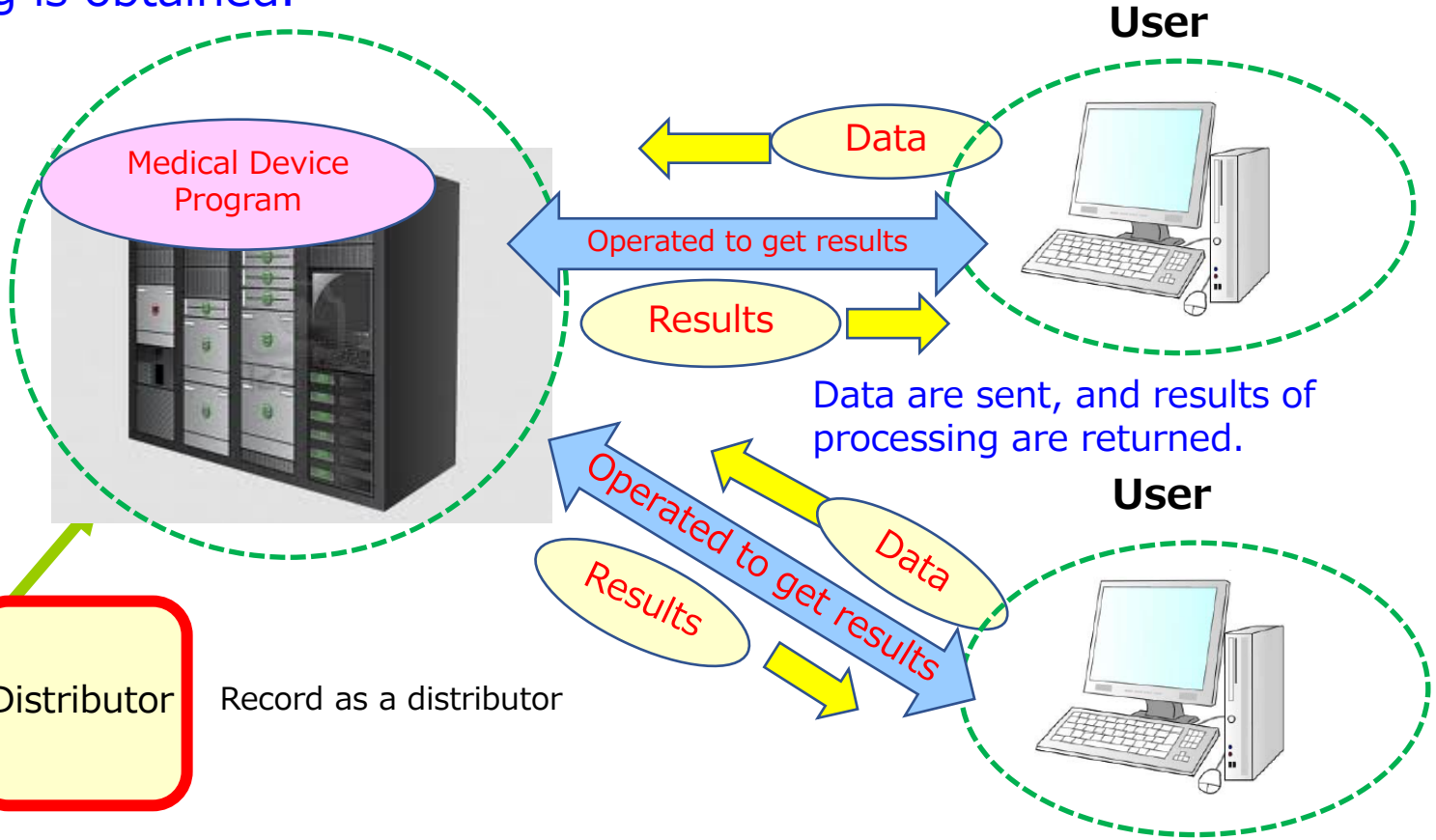
Cloud
(Cloud service providers are not required to have business formats based on the Pharmaceuticals and Medical Devices Law.
What about other laws and regulations?)



5-2 Matters To Be Considered Regarding the Use Environment (2)

The Medical Device Program, placed on a server, is accessed and directly operated by individual PCs so that data are set on it and results of their processing is obtained.

Cloud
(Cloud service providers are not required to have business formats based on the Pharmaceuticals and Medical Devices Law.
What about other laws and regulations?)

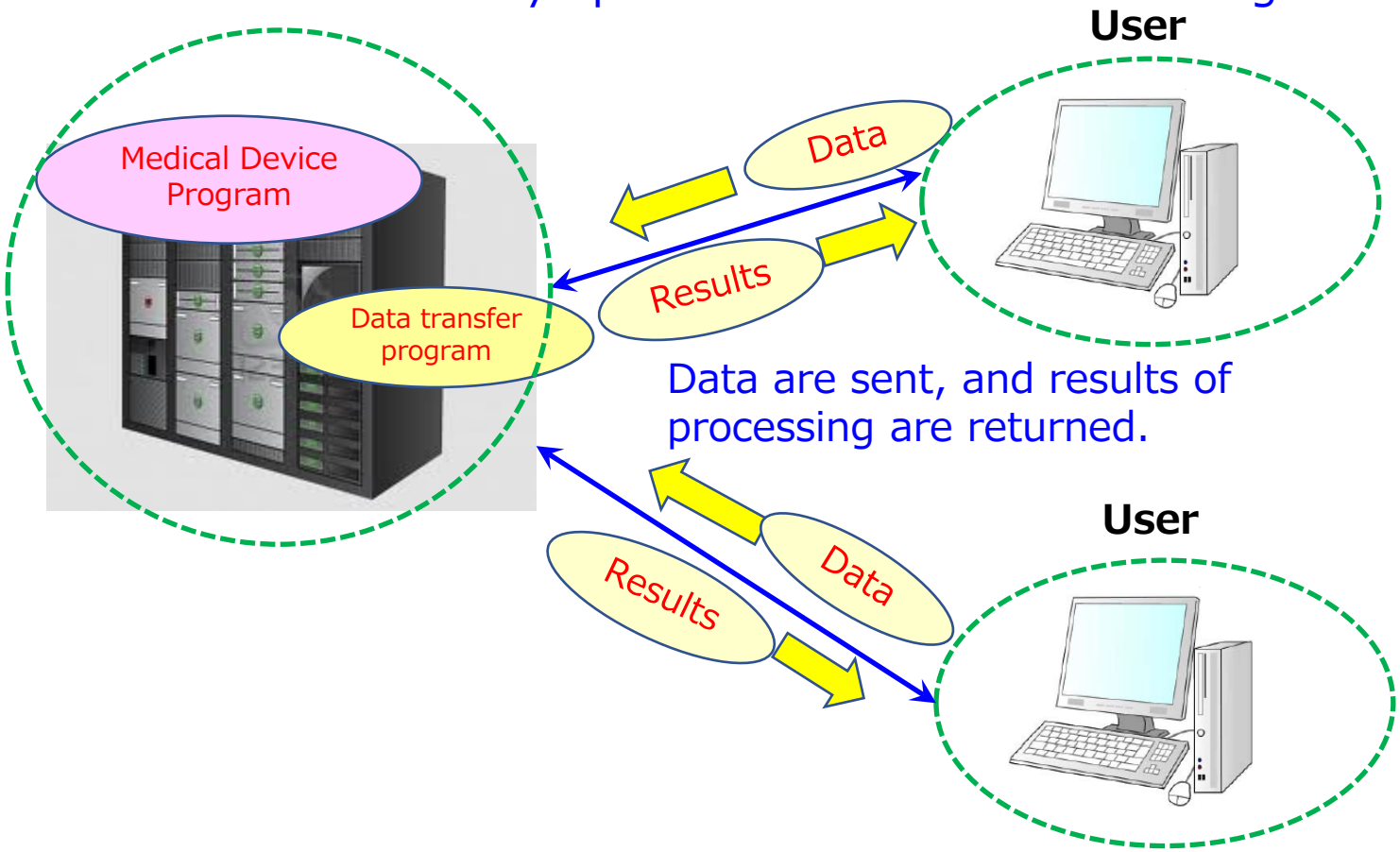


5-3 Matters To Be Considered Regarding the Use Environment (3)

(To be decided)

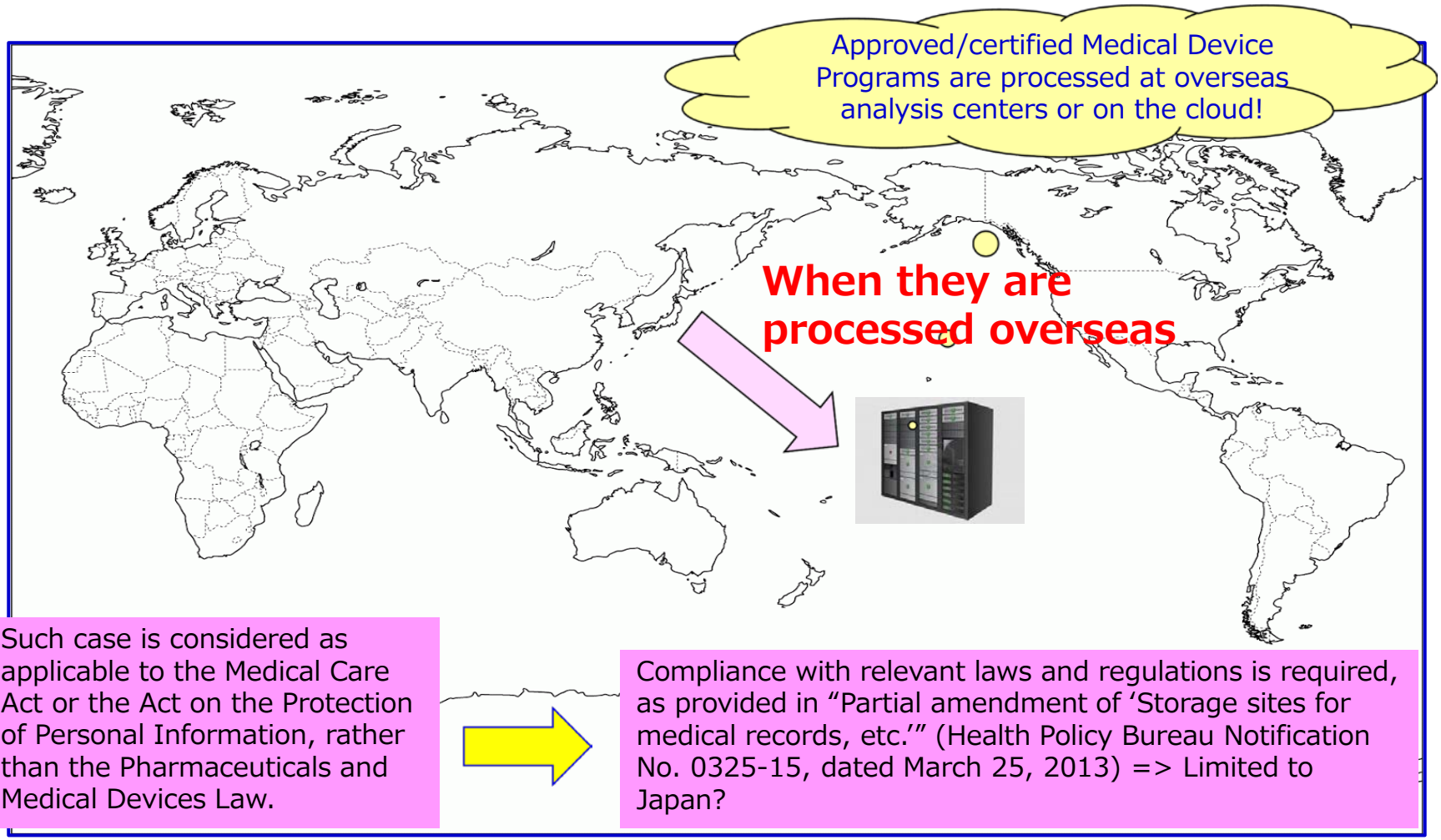
Individual PCs send data, using a transfer program, to the Medical Device Program placed on a server, and then the program processes them to return results. Users do not directly operate the Medical Device Program.

Cloud
(Cloud service providers are not required to have business formats based on the Pharmaceuticals and Medical Devices Law.
What about other laws and regulations?)



5-4 Use, etc. of the Medical Device Program

(To be decided)



Such case is considered as applicable to the Medical Care Act or the Act on the Protection of Personal Information, rather than the Pharmaceuticals and Medical Devices Law.

Compliance with relevant laws and regulations is required, as provided in “Partial amendment of ‘Storage sites for medical records, etc.’” (Health Policy Bureau Notification No. 0325-15, dated March 25, 2013) => Limited to Japan?

Reference C_1: Medical Device Program Approval/Certification Results

Approved products: as of June 29 2018; Certified products: as of April 30, 2018

Category	Classification	Approved			Certified			Total
		Manufacturer/ distributor	Overseas	Total	Manufacturer/ distributor	Overseas	Total	
Programs for disease treatment	III	25	1	26				35
	II	8	1	9				
Programs for disease diagnosis	II	5	2	7	180+1	10+2	193+3	200+3
Total		38	4	42	180+1	10+2	193+3	**235+3**

Ref. C_2 Ref. C_3

Note: Of the certified products, three were reassigned to generic names, after the enforcement of the regulatory revision.
(One of the three is "Program for holter analysis devices" in 2010; the remaining two are "Program for general-purpose diagnostic imaging device workstations" in 2014 and 2015.)

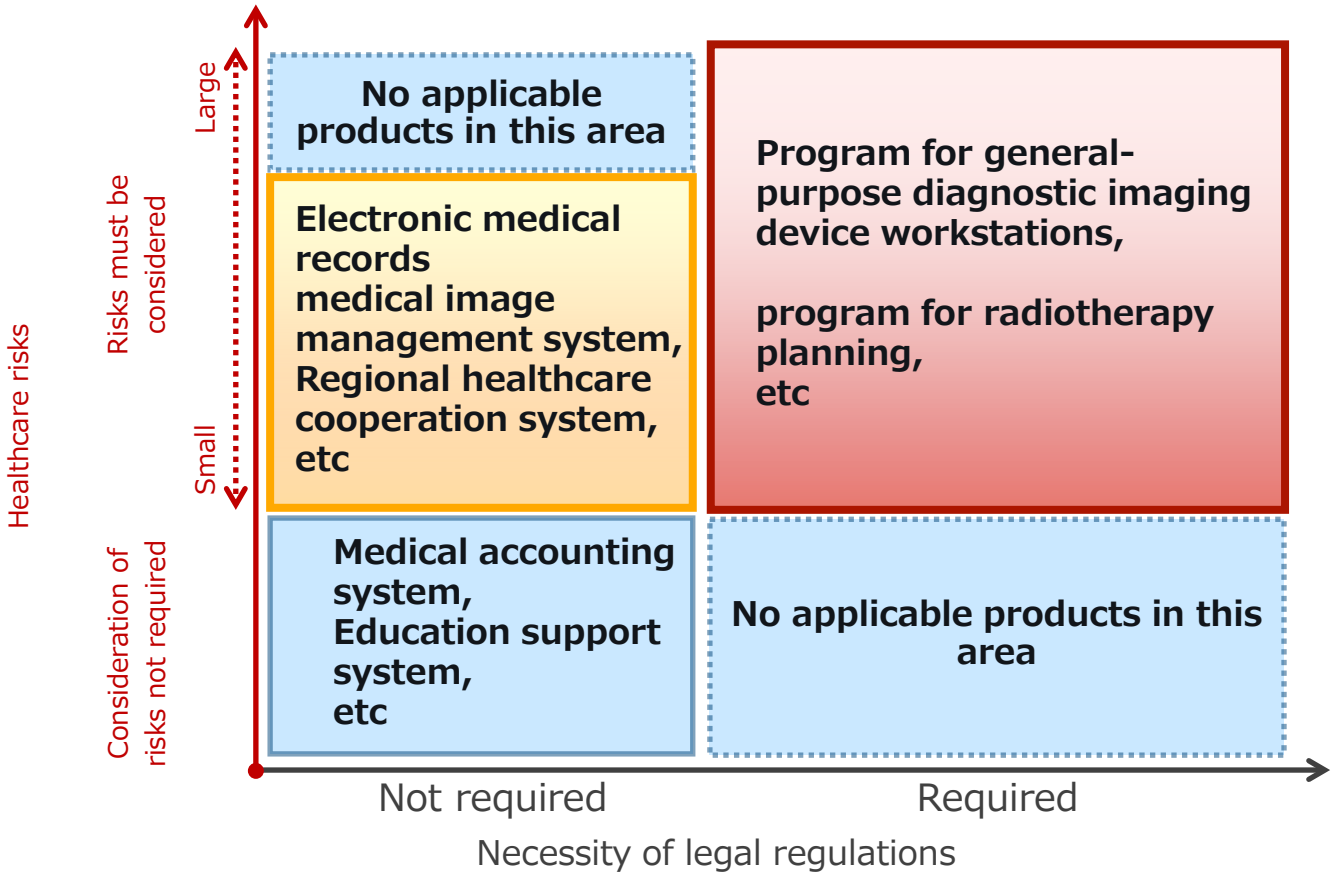
Medical Software

GHS
Good Health Software

6. Software Used in the Healthcare Field

Conceptual classification of medical software products

(from the viewpoint regulations and risks)



Source: Good Health Software Promotion Council

6-1 Consideration for Risks in Health Software

- Even software outside the scope of legal regulations has certain levels of risk in its use in healthcare settings. It is necessary to consider/examine such risks specific to the healthcare field.
- Since there are no public regulations/specifications, the industry establishes voluntary standards/rules and conducts activities to deploy their operational management and expand products declared as compliant to such standards.
- Such activities are carried out for

GHS
Good Health Software

(In 2014, the Good Health Software was established, and its development guidelines Ver. 1.0.0 was publicized.)

6-2 GHS (Activities)

- Establishment/revision of GHS Development Guidelines
  → Provision of education and promotion activities
  → Publication of compliant products and their promotion
  Such processes are conducted consistently.

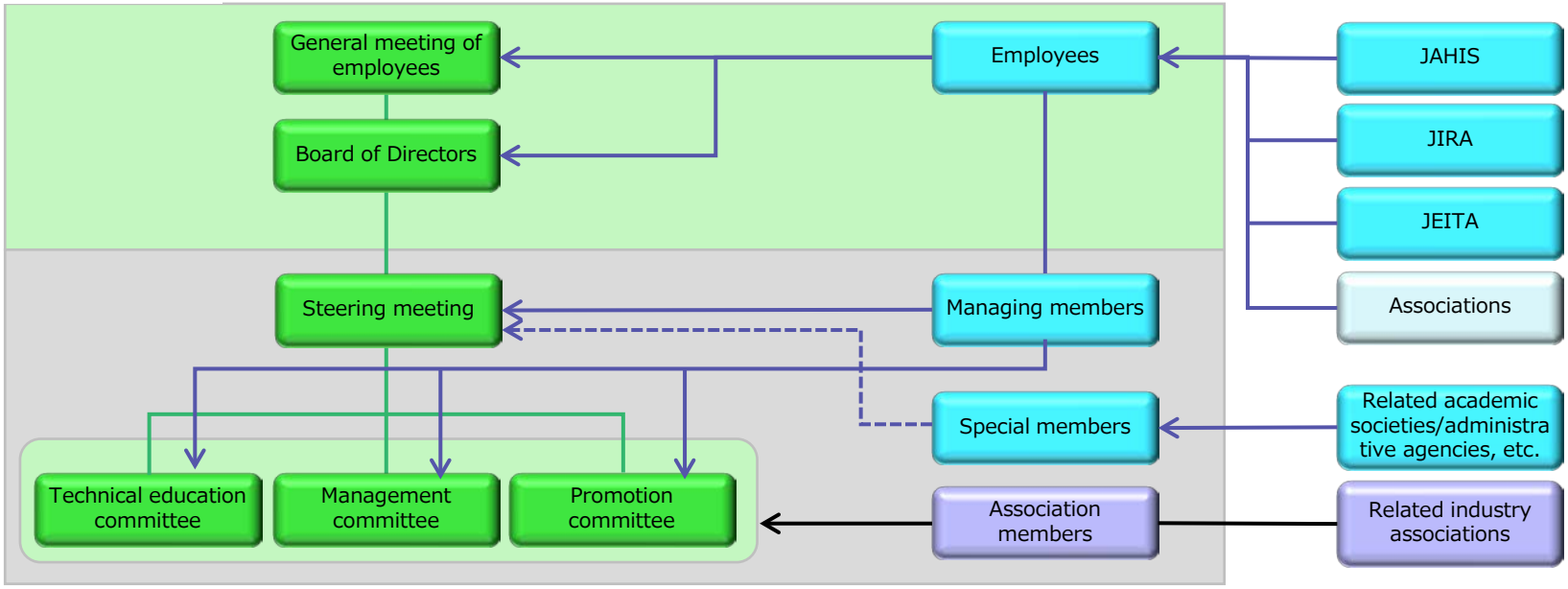
Source: Good Health Software Promotion Council

6-3 GHS (Organization)

- The Good Health Software (GHS) was established in 2014, on the basis of 3 industrial associations in the medical device industry.
- GHS is pressing forward with initiatives in providing excellent products to users (patients and healthcare providers), taking into consideration safety risks, which are expected to increase in healthcare software to be approved outside the scope of legal regulations going forward.

Organization of the Good Health Software

Organization



Source: Good Health Software Promotion Council

7-1 GHS Development Guidelines

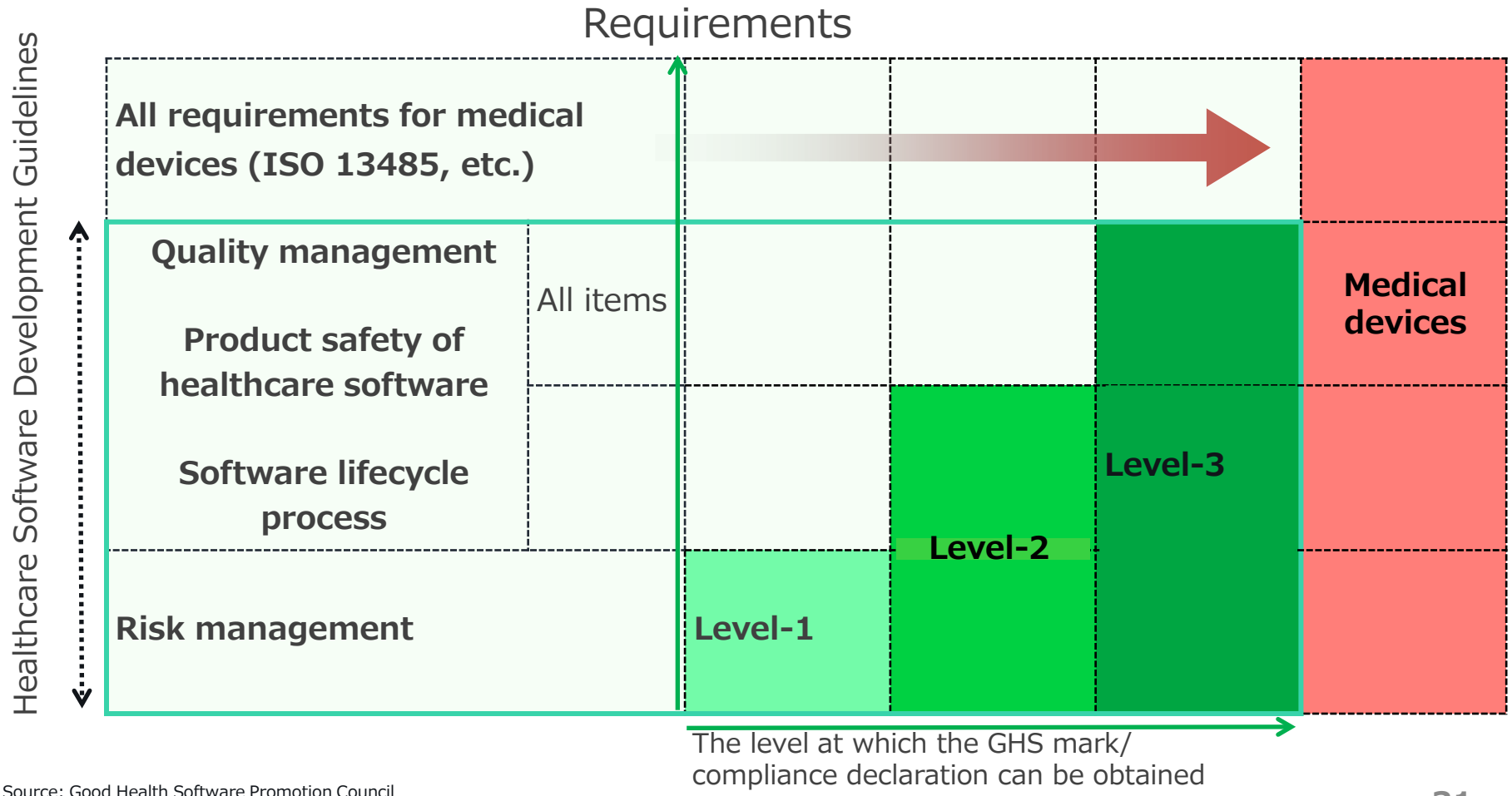
- Category classification, recommended requirements, and a list of international standards for reference

Category	Recommended requirements	International standards for reference
Quality management	Design development process	ISO 9001:2008 (JIS Q 9001:2008) Quality Management System – Requirements
Risk management	- Risk analysis - Risk assessment - Risk control - Residual risk assessment - Management of development stages and post-marketing information[Note]	ISO 14971:2007 (JIS T 14971:2012) Medical devices – Application of risk management to medical devices
Product safety of healthcare software	- Analysis and definition of user requirements - Software validation - Identification of software and preparation of related documents	IEC 82304-1:2016 (JIS T 82304:2017)
Software lifecycle process	- Software development plan - Analysis of software requirements - Software configuration management process	IEC 62304:2006 (JIS T 2304:2012) Medical device software–- Software lifecycle process

Source: Good Health Software Promotion Council

7-2 GHS Development Guidelines

- Classification of levels of healthcare software development guidelines and compliance declaration
- According to potential risks in the product, 3 levels of compliance have been prepared.



Source: Good Health Software Promotion Council

7-3 GHS Development Guidelines


GHS
Good Health Software

ヘルスソフトウェア開発ガイドライン
（GHS 開発ガイドライン）

Ver. 1.00 2014.08.01

一般社団法人ヘルスソフトウェア推進協議会

【目次】

Source: Good Health Software Promotion Council

8-1 Procedures for Compliance Declaration

GHS has established voluntary standards/rules.

- Compliance declaration is made possible by implementing to the established development guidelines and procedures for assessing compliance.

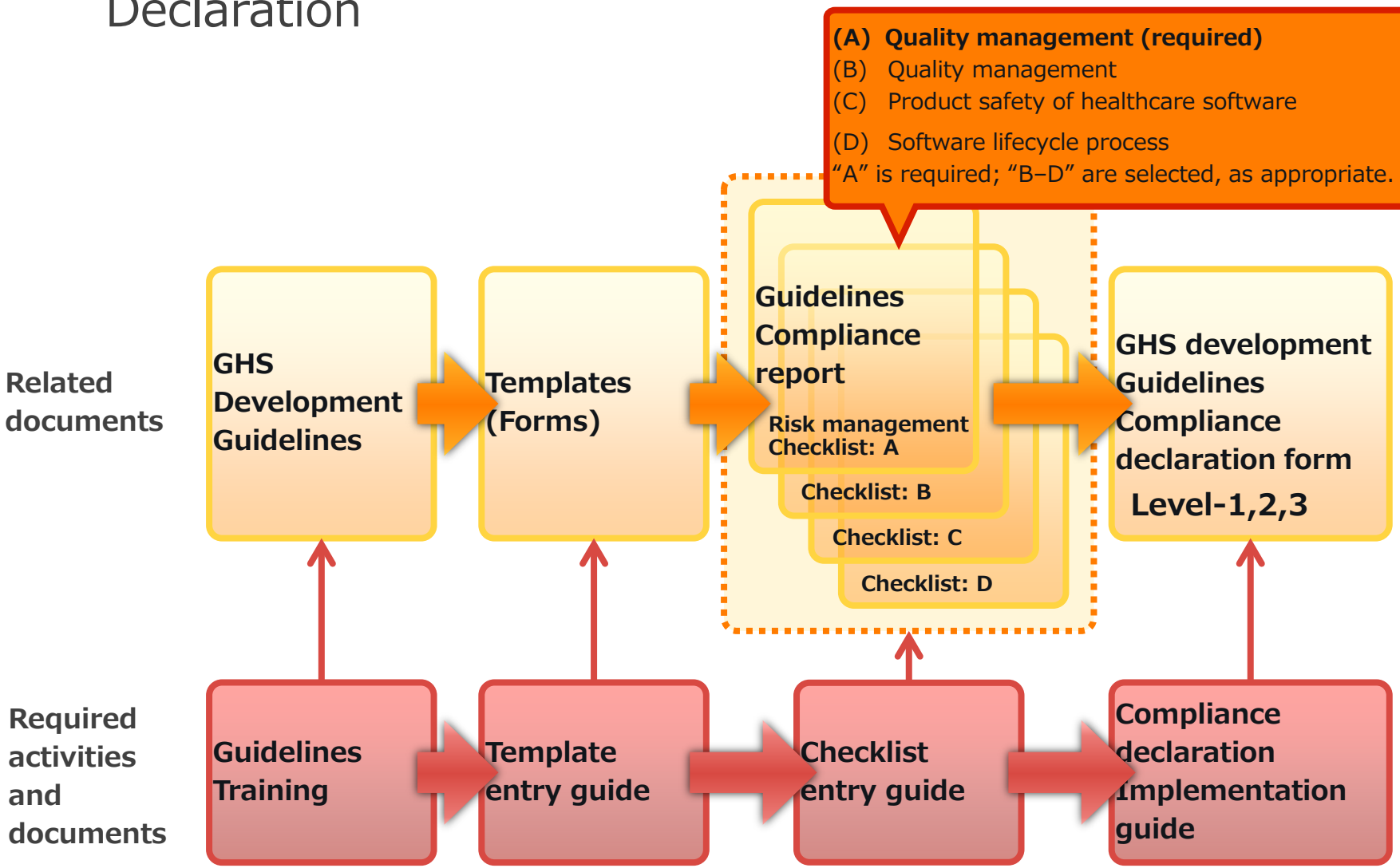
Compliance with the development guidelines is assessed using a check sheet.

- A check sheet provided by GHS is used to assess whether or not the product development/evaluation process conforms to the development guidelines.

Requesting the registration of the compliance declaration and a permission to use the GHS mark

- Request is made for the registration of GHS development guidelines compliance declaration.
- When the contents of submitted documents are checked and found with no problems, a notification of approval is issued.
- At the same time, a permission to use the GHS logo and the logo data are provided.
- A compliance declaration form with the GHS mark is submitted to the GHS council.

8-2 Documents and Activities Related to Compliance Declaration



Source: Good Health Software Promotion Council

8-3 Compliance Declaration Reflecting Product/Market Conditions

Compliance with Healthcare Software Development Guidelines

- Unrestricted by the Pharmaceuticals and Medical Devices Law, compliance with healthcare software guidelines is a voluntary declaration (outside the scope of legal regulations).
- We are seeing a recent trend of having even non-medical device products, which may be used in healthcare/medical fields, undergo procedures for risk analysis and preventive examination.
- Product development based on risk management is proactively defensive activities for products and its manufacturer.
- (However,) It will be difficult for newcomers to the healthcare industry and companies who have product development experience only in non-medical device products to comply with a full set of healthcare software development guidelines from the beginning.

3 levels of GHS Compliance Have Been Prepared

- 3 levels of compliance level have been prepared, in consideration of changes in product function/product use situations and the content of potential risks.
- Starting from Level-1: Risk management, compliance level can be enhanced incrementally.

8-4 GHS Mark Usage Criteria

- **The GHS mark can be used/displayed on applicable products as follows:**
  - ① On the product main unit
  - ② On the product package
  - ③ On the displayed screen of the product
  - ④ In the product IFU
  - ⑤ In product catalogs, package insert/labels, etc.
  - ⑥ In product websites/promotion videos
  - ⑦ In product publicity/advertising
  - ⑧ In other locations approved by the GHS council
- **The registration number is required to be displayed in a designated location.**
- **The mark can be used only for the registered product.**

Ref. D

Horizontal type

Vertical type

Source: Good Health Software Promotion Council

Thank you for your attention.

References

Reference A: Basic concept on the applicability of radiotherapy-related programs to medical devices

Based on the function of each device, the applicability to the Medical Device Program was organized and published.

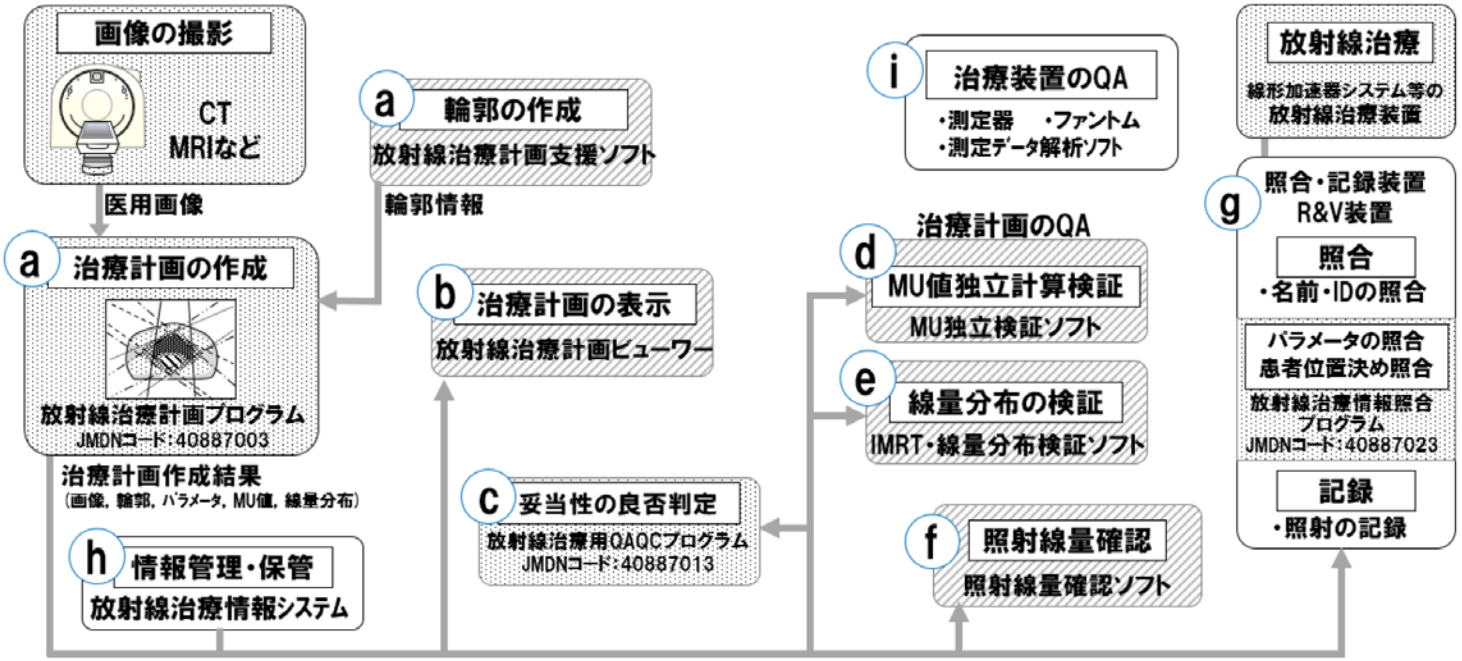


図１：放射線治療に関係するプログラムの全体構成及びそれぞれが備える機能

JIRA HP http://www.jira-net.or.jp/commission/houki_anzen/info1.html#act02

B_1: Additional Generic Names for the Medical Device Program (I)

As of the enforcement of the revised law (November 2014)

クラス分類告示			コード	一般的名称 １５０名称	クラス分類	特定保守	設置管理	修理区分
別表第1	別表第2	別表第3						
	1806		37626032	汎用Ｘ線診断装置用プログラム	Ⅱ	－		－
	1807		37626042	汎用一体型Ｘ線診断装置用プログラム	Ⅱ	－		－
	1808		70001012	乳房撮影組合せ型Ｘ線診断装置用プログラム	Ⅱ	－		－
	1809		37621032	汎用Ｘ線透視診断装置用プログラム	Ⅱ	－		－
	1810		37621042	汎用一体型Ｘ線透視診断装置用プログラム	Ⅱ	－		－
	1811		37612012	循環器用Ｘ線透視診断装置用プログラム	Ⅱ	－		－
	1812		37630012	乳房用Ｘ線診断装置用プログラム	Ⅱ	－		－
	1813		37615012	泌尿器・婦人科用Ｘ線透視診断装置用プログラム	Ⅱ	－		－
	1814		37675032	腹部集団検診用Ｘ線診断装置用プログラム	Ⅱ	－		－
	1815		37627052	胸部集団検診用Ｘ線診断装置用プログラム	Ⅱ	－		－
	1816		37627062	胸･腹部集団検診用Ｘ線診断装置用プログラム	Ⅱ	－		－
	1817		37675042	腹部集団検診用一体型Ｘ線診断装置用プログラム	Ⅱ	－		－
	1818		37627072	胸部集団検診用一体型Ｘ線診断装置用プログラム	Ⅱ	－		－
	1819		37627082	胸･腹部集団検診用一体型Ｘ線診断装置用プログラム	Ⅱ	－		－
	1820		70002012	歯科用パノラマＸ線診断装置用プログラム	Ⅱ	－		－
	1821		37668012	歯科用パノラマ・断層撮影Ｘ線診断装置用プログラム	Ⅱ	－		－
	1822		37636012	口外汎用歯科Ｘ線診断装置用プログラム	Ⅱ	－		－
	1823		37677032	頭蓋計測用Ｘ線診断装置用プログラム	Ⅱ	－		－
	1824		37677042	頭蓋計測用一体型Ｘ線診断装置用プログラム	Ⅱ	－		－
	1825		37619012	Ｘ線ＣＴ診断装置用プログラム	Ⅱ	－		－
	1826		70006012	アーム型Ｘ線ＣＴ診断装置用プログラム	Ⅱ	－		－
	1827		40640012	ガンマカメラ用プログラム	Ⅱ	－		－
	1828		40642012	ＳＰＥＣＴ装置用プログラム	Ⅱ	－		－
	1829		40644012	核医学診断用ポジトロンＣＴ装置用プログラム	Ⅱ	－		－
	1830		36208012	超音波画像診断装置用プログラム	Ⅱ	－		－
	1831		40779012	超音波骨密度測定装置用プログラム	Ⅱ	－		－
	1832		37611012	ＭＲ装置用プログラム	Ⅱ	－		－

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B_2: Additional Generic Names for the Medical Device Program (II) After the enforcement of the revised law (as of June 2018)

As notified in the MHLW notification No. 422 (October 2015), new names were added, based on applications for approval, and also several times after that.

Note: In case no applicable generic names are found, the manufacturer applies for them describing the situation; when the application has been approved, new generic names (classification, definition, etc.) are designated.

クラス分類告示			コード	一般的名称 19名称	クラス分類	特定保守	設置管理	修理区分
別表第1	別表第2	別表第3						
1111			61215003	ハイリスク薬物動態解析プログラム	Ⅲ	–		–
1112			41049003	腹膜透析用治療計画プログラム	Ⅲ	–		–
1113			40887003	放射線治療計画プログラム	Ⅲ	–		–
1114			40887013	放射線治療用QAQCプログラム	Ⅲ	–		–
1115			71039003	眼科手術用治療計画プログラム	Ⅲ	–		–
1120			71052003	電気刺激治療装置用パラメータ選択プログラム	Ⅲ	–		–
1127			71052003	植込み能動型機器管理用プログラム	Ⅲ	–		–
1141			61777003	生殖細胞系列遺伝子変異解析プログラム（抗悪性腫瘍薬適応判定用）	Ⅲ	–		–
1144			40887023	放射線治療情報照合プログラム	Ⅲ			
	1960		71040002	呼吸装置治療支援プログラム	Ⅱ	–		–
	1961		71041002	骨強度分析プログラム	Ⅱ	–		–
	1962		71042002	コンタクトレンズ選択支援プログラム	Ⅱ	–		–
	1963		71043002	歯科インプラント用治療計画支援プログラム	Ⅱ	–		–
	1964		71044002	歯科矯正用治療支援プログラム	Ⅱ	–		–
	1965		58120002	創外固定器治療計画支援プログラム	Ⅱ	–		–
	1966		71045002	糖尿病診断補助プログラム	Ⅱ	–		–
	1967		71046002	末梢血流量評価プログラム	Ⅱ	–		–
	1968		71047002	ICG検査用画像解析プログラム	Ⅱ	–		–
	1976		61213002	循環動態解析プログラム	Ⅱ	–		–

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Reference C_2: Medical Device Program Approval Status

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(as of June 28, 2018)

一般的名称	H26下	H27上	H27下	H28上	H28下	H29上	H29下	H30上	計
放射線治療計画プログラム			2	2	3	7	1	2	17
呼吸装置治療支援プログラム			2			1			3
創外固定器治療計画支援プログラム			1		1		1		3
腹膜透析用治療計画プログラム				1		1		1	3
眼科手術用治療計画プログラム			1		1				2
ハイリスク薬物動態解析プログラム					1				1
骨強度分析プログラム			1						1
電気刺激治療装置用パラメータ選択プログラム			1						1
汎用画像診断装置ワークステーション用プログラム			1						1
歯科矯正用治療支援プログラム				1					1
植込み能動型機器管理用プログラム				1					1
コンタクトレンズ選択支援プログラム					1				1
循環動態解析プログラム					1				1
ＳＰＥＣＴ装置用プログラム						1			1
糖尿病診断補助プログラム						1			1
手術用ナビゲーションユニット用プログラム							1		1
生殖細胞系列遺伝子変異解析プログラム							1		1
歯科インプラント用治療計画支援プログラム								1	1
放射線治療用ＱＡＱＣプログラム								1	
計	0	0	9	5	8	11	4	5	42

注:　黒:疾病治療用プログラム　　青:疾病診断用プログラム、

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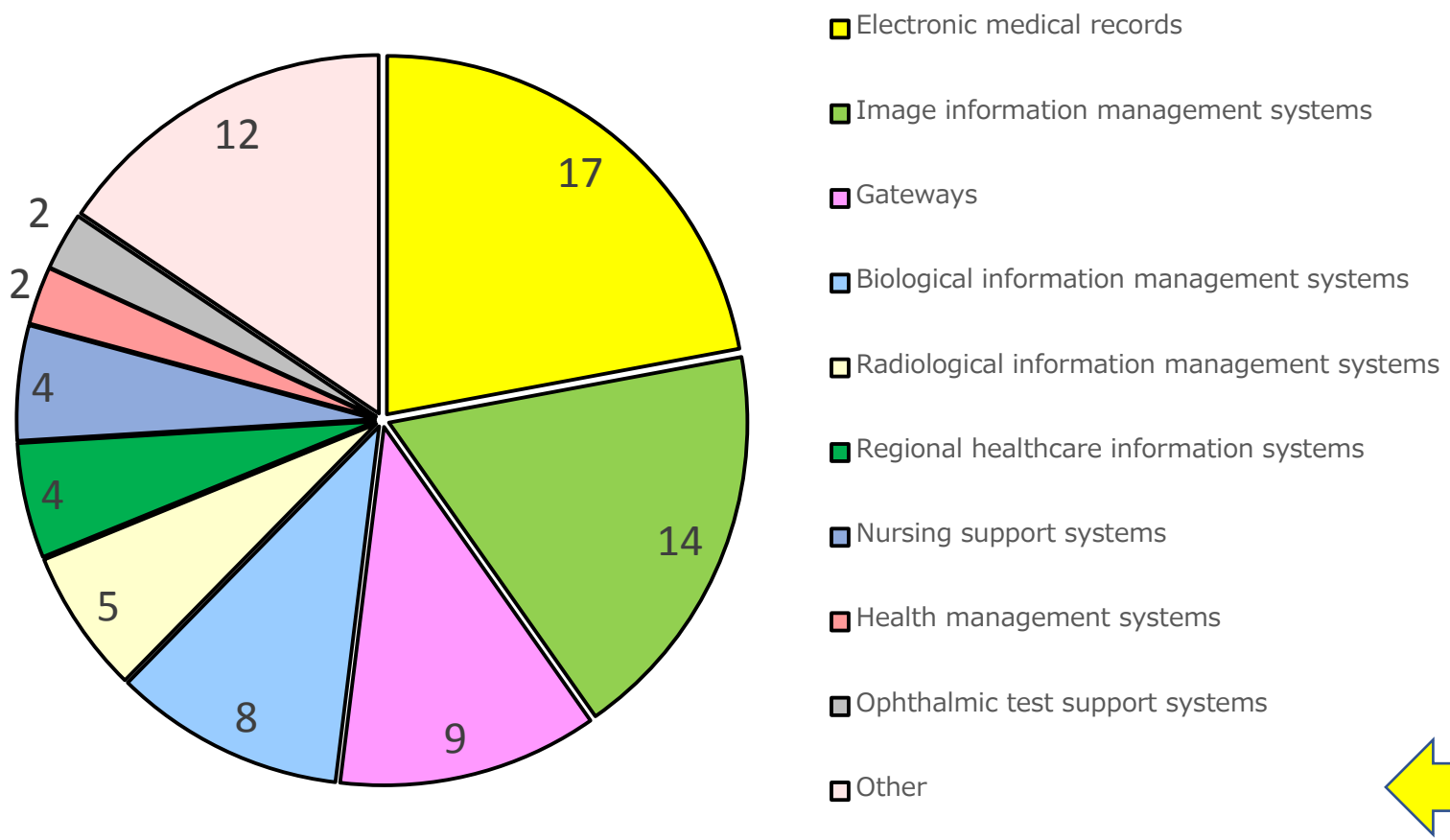
Reference C_3: Medical Device Program Approval Status

(as of April 30, 2018)

一般的名称	H26下	H27上	H27下	H28上	H28下	H29上	H29下	H30上	計
汎用画像診断装置ワークステーション用プログラム	1	40	28	8	8	4	8	3	101
眼撮影装置用プログラム	2	8	2	2			1		15
Ｘ線画像診断装置ワークステーション用プログラム		4	1	1	2	1	2		11
パルスオキシメータ用プログラム		4	2						6
長時間心電用データレコーダ用プログラム		3		2	1				6
眼底カメラ用プログラム		3	1			1			5
自動視野・眼撮影装置用プログラム		2		1	1				4
ホルタ解析装置用プログラム		1			1	1	1		4
睡眠評価装置用プログラム			3			1			4
セントラルモニタ用プログラム				4					4
超音波装置ワークステーション用プログラム		3							3
脳波計用プログラム		2			1				3
Ｘ線ＣＴ診断装置用プログラム		1				1	1		3
医用電子血圧計用プログラム			1			1	1		3
歯科診断用口腔内カメラ用プログラム		1	1						2
発作時心臓活動記録装置用プログラム		1		1					2
骨Ｘ線吸収測定装置用プログラム		1					1		2
ＭＲ装置ワークステーション用プログラム			1			1			2
眼球運動検査装置用プログラム					1	1			2
筋電計用プログラム		1							1
汎用心電計用プログラム		1							1
ＳＰＥＣＴ装置用プログラム			1						1
経皮血中ガス分析装置・パルスオキシメータ組合せ生体現象監視用機器用プログラム			1						1
口外汎用歯科Ｘ線診断装置用プログラム			1						1
歯科用パノラマ・断層撮影Ｘ線診断装置用プログラム			1						1
体成分分析装置用プログラム			1						1
心電図電話伝送装置用プログラム				1					1
多項目モニタ用プログラム				1					1
血圧脈波検査装置用プログラム						1			1
乳房用Ｘ線診断装置用プログラム							1		1
計	3	76	45	21	15	13	17	3	193

Reference D: The Status of GHS Mark Registered Products

- The number of registered products: 77 (June 2018)



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Source: Good Health Software Promotion Council