Administrative Notice
December 22, 2023

To: Prefectural Health Department (Bureau) Pharmaceutical Affairs Section,

Director of Medical Device Evaluation Division, Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare

Questions and Answers (Q&A) on the Application for Confirmation of Change Plans for Medical Devices, Medical Devices Utilizing Artificial Intelligence-Related Technologies, and Program Medical Devices

Regarding the handling of applications for confirmation of change plans for medical devices, in addition to the "Handling of Applications for Confirmation of Change Plans for Medical Devices" (Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare PSEHB/MDED Notification No. 0831-14, dated August 31, 2020), we have provided a collection of Q&A on the handling of application methods, document compilation, in change plan confirmation applications (hereinafter collectively referred to as the "existing Q&A") through the "Q&A on Applications for Confirmation of Change Plans for Medical Devices" (Administrative Contact, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour, and Welfare, dated October 30, 2020), "Q&A on Applications for Confirmation of Change Plans for Medical Devices (Part 2)" (Administrative Contact of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour, and Welfare, dated October 20, 2021), and "Q&A on Applications for Confirmation of Change Plans for Medical Devices Using Artificial Intelligence-Related Technologies" (Administrative Contact of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour, and Welfare, dated March 31, 2022).

The Regulatory Reform Implementation Plan approved by the Cabinet on June 16, 2023, stated that "from the viewpoint of improving the effects of the Change Plan Confirmation Procedure System (IDATEN), Q&A for necessary change plans should be enriched based on specific examples of formats and needs such as startups with little experience in development of medical devices."

Based on this, we have integrated and partially revised the existing Q&A, and revised it as shown in the attachment. Please ensure that you disseminate this information to commercial manufacturers in your jurisdiction.

The existing Q&A above will be repealed by this Administrative Notice.

Appendix

Questions and Answers (Q&A) on the Application for Confirmation of Change Plans for Medical Devices, Medical Devices Utilizing Artificial Intelligence-Related Technologies, and Program Medical Devices

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Abbreviations used	Name
Regulations	Regulation for Enforcement of the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Ministry of Health and Welfare Ordinance No. 1 of 1961)
Notification by Director	"Handling of Application for Confirmation of Change Plan for Medical Devices" (PSEHB/MDED Notification No. 0831-14 by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated August 31, 2020)
Examples of IDATEN	Administrative Notice of the Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour, and Welfare, dated December 22, 2023, "Examples of Descriptions in Application Forms and Attachments for Confirmation of Change Plan for Program Medical Devices"
Office of Medical Devices, PMDA	Office of Medical Devices I, II, or the Office of Program Medical Devices of the Pharmaceuticals and Medical Devices Agency

[Points to consider]

Even when referring to the above notifications, this Q&A, and examples described in IDATEN, if there are any questions when applying for confirmation of the change plan, consult with the Office of Medical Devices, PMDA.

No. 1 Consultation on the scope and application

Q1: (Necessity of predevelopment consultation for medical devices)

Part 1 of the Director's Notification states, "If you wish to confirm a change plan, for the time being, you shall apply for the PMDA's (Pharmaceuticals and Medical Devices Agency) predevelopment consultation for medical devices and receive advice in advance on whether the planned change plan is subject to this notification." However, is it absolutely necessary to apply for a consultation regarding eligibility through the predevelopment consultation for medical devices?

A: Consultation on applicability through a predevelopment consultation for medical devices is intended to initiate communication with the Office of Medical Devices, PMDA at an early stage to smoothly and efficiently confirm applications for the confirmation of change plans and implement changes in accordance with these plans. Therefore, if it is determined that the same applicant has accumulated experience in multiple cases of applying for confirmation of a change plan, it is possible to omit the applicability judgment during the predevelopment consultation for medical devices. If you wish to consult on the applicability through a predevelopment consultation for medical devices, it is advisable to first apply for a general consultation and confirm the sufficiency of the necessary documents for the predevelopment consultation for medical devices, as well as the schedule until the consultation.

Q2: (Timing of application for confirmation of change plan)

When is it possible to confirm the change plan for the medical device for which the approval application was submitted?

A: For a medical device for which an application for approval is submitted, an application for confirmation of the change plan may be submitted when the information necessary for separately making this application is obtained. In this case, the system reception number attached by the PMDA at the time of the medical device approval application is required, in addition to the information necessary for the application to confirm the change plan, as described in the notification from the Director. However, since the application for confirmation of the change plan is intended to apply for and receive confirmation of the change plan for approval items, it should be noted that if the approval items prior to the change are unclear, the discussion on the confirmation application may not proceed.

Q3: (Additional changes after the application for confirmation of the change plan)

After the application for confirmation of the change plan is submitted, how should additional changes be handled when an additional change is made to a part of the change plan during its confirmation by PMDA?

A: Contact the person in charge of confirmation in the Office of Medical Devices of the PMDA for consultation. Depending on the content of the additional changes, it may be necessary to confirm the entire change plan again after the addition, which may take a lot of time to complete. For this reason, the contents of the change plan

should be thoroughly considered before applying for confirmation to ensure that no further changes in the contents will be required after application for confirmation.

No. 2. Matters to be described in the application to confirm the change plan

Q4: (Preparation of the change plan confirmation application form and attachments)

Is it acceptable to prepare the change plan confirmation application form and attachments by referring to various notifications related to the approval application of medical devices in addition to "Points to Consider When Preparing Marketing Approval Application Forms for Medical Devices" (PFSB/ELD Notification No. 1120 (i), dated November 20, 2014) and "Points to Consider When Preparing Attachments of Marketing Approval Application Format for Medical Devices" (PFSB/ELD Notification No. 0120-9, dated January 20, 2015)?

A: Understand the characteristics of the application to confirm the change plan for medical devices and refer to them when making appropriate adjustments.

Q5: (Number of copies of documents to be submitted)

Is it acceptable for the document composition in applications for confirmation of change plans and applications for confirmation of changes to confirmation items of the change plan to consist of the following: one original (application form, copy of approval document, attached documents, supplementary documents, reference documents, and other documents), two copies (application form only), two sets of documents for the confirmation application (for modified medical devices without clinical data and generic medical devices), or one set (for other application categories)?

A: You are correct. If a copy is to be kept by the applicant, prepare an additional copy.

Q6: (Documents for review of online application)

If submission is made online, is it unnecessary to submit the documents (documents for review) to confirm the application for change plans for persons in charge of confirmation in accordance with PSEHB/PED Notification No. 0322-1, etc.?

A: You are correct.

Q7: (How to fill out the confirmation application form for online application)

When a change plan confirmation application is made on the "Web application platform for medical devices" (DWAP), is it acceptable to leave the column for approval items with no scheduled changes blank and submit the progress table, etc., as an attachment to the other remarks column?

A: You are correct.

Q8: (How to fill out the remarks column of the confirmation application form)

If the product for which a partial change approval application is filed is also under approval review, should the application date of the partial change approval be stated in the remarks column?

A: You are correct.

Q9: (How to fill out the confirmation application form)

For columns in which no change is planned from the approval items, is it reasonable to describe them as “No change”?

A: You are correct.

Q10: (How to describe multiple changes)

If more than one change is to be included in the application for confirmation of the change plan, what kind of documents should be prepared for “4. New-Old Comparison Table” in B of Attached Table 1 of the Director’s Notification

A: Prepare a new/old cross-reference table as a multistep comparison table by referring to the following example. Note that if multiple changes included in a change plan are each changed by notifications related to changes in accordance with separate change plans, the comparison table must compare the contents of the changes with the changed items in the notifications related to changes in accordance with the change plans.

(Example)

Item	Current approval items	New			Remarks
		Change (1)	Change (2)	Change (3)	
• • •	• • •	• • •	• • •	• • •	
Shape, structure, and principle	●●●	○○○	No change	No change	To be handled by notification (1)
Raw materials	■■■	No change	□□□	No change	To be handled by notification (2)
• • •	• • •	• • •	• • •	• • •	

* Notification (1): Scheduled to be implemented around (month) in (year), Notification (2): Scheduled to be implemented around (month) in (year)

Q11: (Notification of change of division)

If a change plan confirmation application includes multiple changes, is it possible to implement the confirmation items of the change plan separately by submitting notifications for multiple change plans?

A: Yes. However, note that at the time of application for confirmation of the change plan, it is necessary to clarify the relationship among the contents of each change in advance and compare the change items in the notification related to the change according to the corresponding change plan.

Q12: (Submission of a copy of the marketing business license)

Is it unnecessary to submit a copy of the marketing business license when applying for confirmation of change plans and confirmation of changes to the confirmation items of the change plan?

A: You are correct. If requested by the person in charge of confirmation, a copy should be submitted promptly.

No. 3. Handling of documents to be attached to the application for confirmation of the change plan and points to keep in mind when preparing them

Q13: (Attachments to Attached Table 1)

Regarding the "documents that include information on the reasons for setting the change plan and information on conformity to the basic requirements standards, etc." in "No. 2 Matters to be stated in the application for confirmation of change plan" of the Director's Notification, in which item among the attached documents in Attached Table 1 of the Director's Notification should it be described?

A: The "information on the reasons for setting the change plan and information on conformity to the basic requirements standards" does not necessarily need to be prepared as independent documents, and it is acceptable to include them in "3. Documents related to the change plan" of Attached Table 1, Item (i) of the Director's Notification."

Q14: (Requirements for test planner)

What specific requirements are expected to be met by the phrase "by experienced researchers at a facility with sufficient equipment" in item 1 of the section "No. 3 Handling of documents to be attached to the application for confirmation of change plan and points to keep in mind when preparing them" in the Director's Notification?

A: It shall be assumed that the change plan for the medical device will be formulated by a medical device commercial manufacturer or a manufacturing company responsible for design management based on the technical standards that they typically maintain and that it will be developed in accordance with the rules governing their responsibilities and authority as a commercial manufacturer.

Q15: (Test report)

At the time of submitting the change plan confirmation application, if some or all of the test reports among the supplementary documents to be attached have already been prepared, is it acceptable to attach either the test protocol or the test report? Are the test results in the attached report confirmed?

A: If the test report includes content that allows verification of the protocols, such as the implementation procedures of the change plan, it is acceptable to attach the test report. However, since the test results recorded in the test report are not subject to review in the change plan confirmation application, if a test report is attached at the time of the change plan confirmation application, its test results will not be reviewed but will only be treated as reference materials.

Q16: (Handling of declaration)

For change plan confirmation applications for medical devices, materials are prepared at the stage of change planning. How should a declaration of conformity and a declaration on validation (sterilization validation) assure the sterility assurance level (SAL)?

A: For the declaration of conformity, explain the standards that will be declared after the implementation of the change plan in the section "Conformity to Basic Requirements Standards" of the attached documents. For the sterilization validation declaration, provide an overview of the sterilization validation process in the section "Information on Sterilization Methods" of the attached documents. However, it is not required to attach a draft of the declaration of conformity or a draft of the statement on sterilization conditions related to the assurance of the Sterility Assurance Level (SAL) as supplementary documents. Nonetheless, when submitting the notification form related to the changes based on the change plan, attach documents reflecting the test results obtained through the implementation of the change plan and submit them along with the relevant supplementary documents, such as the declaration of conformity, test reports, statements related to original documents, affidavits on stability and statements on SAL assurance, as appropriate.

Q17: (Handling of summary report on compliance)

Is it acceptable to handle the summary report on conformance to the software life cycle process at the time of application for confirmation of the change plan for the medical device in accordance with the handling of the declaration in QA 16?

A: You are correct. However, in past marketing approval reviews for medical devices, the status of actions taken for the software life cycle process should be explained, and if approved, the in-house document number, etc. should be described in an attachment to the application for confirmation of medical device change plans (Refer to page 75 of Examples of description in IDATEN).

Q18: (Notes on the descriptions in the progress table)

Are there points to consider when preparing the progress table to be attached to the application for confirmation of the change plan? In addition, are there points to consider when preparing a progress table if the contents of changes at multiple stages are included?

A: In the application for confirmation of the change plan, a code different from those for partial change approval and minor change notification should be used and entered in the change section related to the change plan. For example, if a "○" stamp has been used in the past, a "●" stamp should be used to indicate changes in a change plan confirmation application. In addition, "Change (1)" and "Change (2)" etc. should be added to clarify that the timing of implementation of the change is different when the contents of change of multiple stages are included (refer to Attachment 1).

Q19: (How to fill out the progress table in the case of discontinuation, abolition, etc.)

Is it necessary to leave the process related to the confirmation of the change plan in the progress table of notifications related to changes according to the change plan? If the change plan is to be discontinued or abolished, does it need to be deleted from the progress table?

A: The progress table is a history of previous pharmaceutical affairs procedures that were taken before the said pharmaceutical affairs procedure when implementing pharmaceutical affairs procedures, such as an application for partial change in approval items. Therefore, it is necessary to prepare the progress table regardless of whether the change plan has been discontinued or abolished.

Q20: (Form No. 63-19-9)

When applying for confirmation of the change plan, is it necessary to submit Form 63-19-9 in addition to Form 63-19-2?

A: It is necessary. A copy of the fee receipt, such as the receipt of the fee transfer, should be attached to Form No. 63-19-9 and submitted.

No. 4. Handling application to confirm the change plan

Q21: (Protocol consultation for medical devices)

Is it acceptable to apply for a medical device protocol consultation instead of a predevelopment consultation for medical devices if the contents related to the test protocol in the medical device change plan are confirmed among the confirmation items of the change plan?

A: It is possible to confirm the applicability of the requirements of the procedure system for confirmation of medical device change plans at a predevelopment consultation for medical devices, but if you wish to have a consultation on the test protocol in medical device change plans, please apply for a medical device protocol consultation.

Q22: (Necessity of protocol consultation for medical devices)

Is protocol consultation for medical devices essential?

A: Consultation is optional. If you wish to have a consultation on the test protocol before making the application for confirmation of the change plan, please use the Medical Device Protocol Consultation.

Q23: (Change plan for multiple changes)

Can multiple changes be included in the application to confirm the change plan?

A: Yes. However, if more than one change is included in a single application for confirmation of the change plan, the relationship between each change should be clarified and the documents for the application for confirmation of the change plan should be summarized.

Q24: (Changes requiring clinical evaluation)

The scope of changes that can be made in accordance with the change plan shown in Article 114-45-12, Paragraph 2 of the Regulations is limited to changes listed in Article 12, Paragraph 1, Item 1 (a) - (5) to (9) of the Ordinance on Fees. Is it possible to receive confirmation of the change plan for changes that require clinical evaluation?

A: Changes that require clinical evaluation may still be verified. However, an application for the approval of partial changes must be submitted with regard to the application for changes. In this case, the PMDA shall conduct a document-based or on-site inspection to determine whether the change complies with the change plan.

Q25: (Scope of clinical evaluation)

Does the “clinical evaluation” in QA6 refer to a clinical study in the category of new or improved medical devices (with clinical data)?

A: You are correct.

Q26: (Multiple proprietary names)

For products with multiple proprietary names, how should a confirmation application for a change plan and a notification for changes in accordance with the change plan be made for parent and child products?

A: It is acceptable to apply for confirmation of the change plan only for the parent product. When making an application for confirmation of the change plan for the parent product, enter the proprietary name and approval number related to the child product in the remarks column of the application form. In addition, the notification for changes in accordance with the change plan shall be submitted only for the parent product, and for the child product, a minor change notification shall be submitted within 30 days from the initial date, reckoning from the date when the approval items are changed by the notification for changes in the parent product, in accordance with the change plan. In the remarks column of the minor change notification for a child product, in addition to changes in approval items associated with the notification related to changes in accordance with the change plan for the parent product, enter the proprietary name of the parent product, approval number, change plan confirmation number, date of confirmation of the change plan, and date of notification related to changes in accordance with the corresponding change plan.

Q27: (Application of multiple products)

When the same change plan is applied to multiple products, is it acceptable to apply for the confirmation application and notification of the change plan for the representative product and submit the minor change notification for the remaining products?

A: The change plan is related to partial changes in approval items for approved products, and even if the change is similar, it is necessary to receive confirmation for each product, similar to the marketing approval application.

No. 5. Handling changes in the change plan

Q28: (Effective period)

Will the effective period for determining the confirmation items of the change plan be set?

A: The effective period for the confirmation items of the change plan is not set.

Q29: (Consultation on change of confirmation items of the change plan)

It is stipulated that if there is any change in the confirmation items of the change plan, consultation should be made with the PMDA as needed until a separate notification is made. What type of consultation should be conducted specifically?

A: If there is any change in the confirmation items of the change plan, please contact the Office of Medical Devices, PMDA.

Q30: (Application/Notification for Other Changes)

Is it acceptable to make a partial change approval application or a notification of minor changes in the approval items if other changes are required for the approval items of the medical device after the change plan is confirmed?

A: Yes. However, the necessity of changing the confirmation items of the change plan in association with the change in approval items shall be examined, and the change procedure should be followed as necessary. A simple consultation for confirmation should be applied for before the notification of changes by the PMDA to determine whether it is necessary to make a minor change notification for the confirmation items of the change plan or a partial change confirmation application for the confirmation items of the change plan.

Q31: (Consultation on change of confirmation items of the change plan)

When making a change in the confirmation items of the change plan, is it necessary to receive a simple consultation for confirmation before the notification of changes to determine whether it is appropriate to handle it by submitting a minor change notification for the confirmation items of the change plan, rather than applying for the confirmation of changes to the confirmation items of the change plan?

A: You are correct. Only when the appropriateness of the actions taken based on the minor change notification for confirmation items of the change plan is confirmed in the simple consultation for confirmation before the notification of changes, are the actions based on the minor change notification for confirmation items of the change plan permitted. In other cases, a confirmation of changes to the confirmation items of the change plan is required.

Q32: (Consultation on change of confirmation items of the change plan)

When a partial change approval application or a minor change notification of approval items is made for other changes after the change plan is confirmed and the change plan

is subsequently discontinued or abolished, is it necessary to have a simple consultation for confirmation before the notification of changes?

A: A simple consultation for confirmation before the notification of changes is not required when the change plan is discontinued or abolished in association with the approval of a partial change or minor change notification of approval items.

Q33: (Procedure after confirmation of change plan)

If other changes in approval items of the medical device are required after confirmation of the change plan, is there no need to take procedures for the parts with “no change” in the change plan?

A: You are correct.

Q34: (Change of test protocol)

Is it necessary to submit a change application for the confirmation items of the change plan if there is a change in the test protocol for implementing the change plan, even though there is no change in the content of the planned change of the confirmation items?

A: Depending on the degree of change in the test protocol, an application to approve changes in the confirmation items of the change plan may be required. Therefore, it is necessary to consider the effects of changes to the test protocol on the change plan and select appropriate procedures. Contact the Office of Medical Devices, PMDA.

Q35: (Necessity of reporting of discontinuation/abolition)

When the change plan is discontinued or abolished after confirmation, is it necessary to report the discontinuation or abolishment to the Minister of Health, Labour, and Welfare?

A: If the change plan is discontinued or abolished due to post-marketing failure, etc., after confirmation, it is necessary to conduct the required reporting, such as reporting of post-marketing failure. However, it is not necessary to report the discontinuation or abolition of the change plan to the Minister of Health, Labour and Welfare.

No. 6. Handling changes according to the change plan

Q36: (Timing of prenotification consultation)

When is the deadline for application for a prenotification consultation related to notification in accordance with the change plan if data are collected according to the confirmation items of the change plan?

A: No special deadline was set. However, it is desirable to apply for prenotification consultation early to ensure smooth notification.

Q37: (Timing of notification)

When a change notification is submitted in accordance with the change plan, is it acceptable to set the date of the change as the time of the change or the time of release of the product manufactured with the change and submit it 30 days before the time of the change?

A: You are correct. A change notification form that conforms to the change plan may be submitted 30 days before the change.

Q38: (Date of notification/change)

Is it acceptable to set a period of more than 30 days between the date of submission of a notification in accordance with the change plan and the date of change in approval items due to factors such as the mailing period for notification forms, the date of receipt by the PMDA, or production adjustment of products? In this case, how will the date of submission and the date of receipt by the PMDA, as described in the notification form, be handled?

A: It is acceptable for a commercial manufacturer to make a notification by setting a date with a margin of 30 days or more from the date of receipt by the PMDA to the date of change in approved items. In the case of a notification related to a change in accordance with the change plan, the date of the notification and the date of the change should be specified. When a notification of changes according to the change plan is submitted, it is desirable to contact the Office of Medical Devices (PMDA) in advance.

Q39: (Points to consider for notification forms)

Are there points to be considered when preparing documents related to the notification form of changes in accordance with the change plan?

A: When submitting a notification form of changes in accordance with the change plan, it is desirable to attach a document (see Attachment 2) that shows the outline of the added content to the document attached at the time of application for confirmation of the change plan.

Q40: (Attachment of consultation record)

If a prenotification consultation for medical devices IDATEN (including simple consultation for confirmation before notification of changes for medical devices/in

vitro diagnostics) is held, is it necessary to attach the consultation record as a document to be attached to the notification for changes in accordance with the change plan?

A: It is acceptable to enter the date of consultation and the receipt number in the remarks column of the notification form.

Q41: (Inspection of the reliability of the test)

Are the documents showing the test results and the documents related to the contents of the changes, which are attached to the notification of changes in accordance with the change plan, inspected by the PMDA?

A: As shown in Section 3 of the Director's Notification, to confirm that the documents have been collected and prepared based on the provisions of Article 114-22 of the Regulations, the submission of documents required in the reliability inspection may be required. Therefore, it is necessary to make these documents available for immediate submission.

Q42: (Notification of unconfirmed changes)

When submitting a notification of changes in accordance with the change plan, is it acceptable to include changes that can be made by a minor change notification?

A: Changes not confirmed as confirmation items of the change plan cannot be included in the notification related to such changes. Depending on the content of the changes, appropriate procedures should be performed separately. Consult the Office of Medical Devices of the PMDA if any change is made according to the change plan.

Q43: (Confirmation of notification)

Is it acceptable to consider that the notification has been confirmed by the PMDA if the PMDA has not communicated within 30 days after the notification related to the change in accordance with the change plan?

A: You are correct.

Q44: (Doubt about notification)

Is it sufficient to confirm the notifier's procedures, etc., with the PMDA on a case-by-case basis, in the event that doubts regarding the content of said notification arise upon confirmation by the PMDA after notification related to changes made in accordance with the change plan?

A: It is acceptable to confirm the procedures, etc., of the notifier with the person in charge of confirmation at the Office of Medical Devices, PMDA. If it is determined necessary to modify the notification content, the person in charge of confirmation will notify the notifier of the necessary modification. Since the notification form may need to be replaced depending on the contents of the correction, procedures, etc. should be confirmed by the person in charge of confirmation.

Q45: (Necessity of prenotification consultation for medical devices IDATEN)

Is it essential to hold a prenotification consultation for medical devices IDATEN (including simple consultation for confirmation before notification of changes in medical devices or in vitro diagnostics)?

A: Consultation is optional. If specific achievement criteria, such as specifying the scope of application for confirmation of the change plan that can be processed by notification (acceptance criteria in the test plan), are set and the expected results from the plan are obtained, consultation before the notification of the medical device IDATEN is not required. However, if the results as scheduled could not be obtained, for example, the results different from those expected from the plan were obtained, utilize the consultation before the notification of the medical device IDATEN.

Q46: (Details of prenotification consultation for medical devices IDATEN)

At a prenotification consultation for medical devices IDATEN, is it possible to determine whether a partial change approval application or a minor change notification is applicable based on the contents of the change plan?

A: A prenotification consultation for medical devices IDATEN is intended to discuss whether or not it is possible to take actions by the notification of the change prior to the change according to the change plan based on the change plan confirmation procedure system. Regarding whether the request corresponds to a partial change approval application or a minor change notification, a simple consultation must be submitted separately.

Q47: (Handling of unachieved performance goal after change)

Can a change notification be submitted in accordance with the change plan if the performance goal, which was previously confirmed in the change plan, is not achieved by a very small margin?

A: In principle, if the test results do not meet the performance goal, the notification of changes in accordance with the change plan is not permitted.

Q48: (Acceptance criteria)

Notification by the Division Director No. 5-1 stipulates that the scope of notification due to changes in accordance with the change plan or specific cases, etc., requiring a partial change approval application, should be notified separately. Is there any criterion that the applicant can adopt until such a notification is issued?

A: To make it possible to submit notification forms related to changes according to the change plan, specific acceptance criteria should be clarified in the test plan at the time of application for confirmation of the change plan so that when test results are obtained, the results can be judged without discussion.

No. 7. Medical devices that use artificial intelligence-related technologies

Q49: (Definition of medical devices utilizing artificial intelligence-related technologies)

Do the definition of "Medical devices (limited to those utilizing artificial intelligence-related technologies)" specified in Article 114-45-2, Paragraph 3, Item 2 of the Regulations and the scope cover only the medical device program, and are medical devices tangible, including hardware excluded?

A: "Medical devices (limited to those utilizing technologies related to artificial intelligence)." is assumed to be a medical device using a program established through machine learning, including deep learning as the main function. The range of concepts may change as technology advances in the future. In addition, "medical devices that are tangible objects including hardware" also apply to devices that utilize artificial intelligence-related technologies to realize the functions of medical devices.

Q50: (Using artificial intelligence-related technology in design or manufacturing)

Regarding "Medical devices (limited to those utilizing technologies related to artificial intelligence.)," are those using artificial intelligence-related technologies in the design or manufacturing subject to the review?

A: It does not include programs built using artificial intelligence technology in medical devices, nor those designed or manufactured with artificial intelligence technology.

Q51: (Handling of changes not related to artificial intelligence technology)

With regard to "Medical devices (limited to those utilizing technologies related to artificial intelligence."), is it necessary to follow Article 114-45-2, Paragraph 3, Item 2 of the Regulations when the change is not related to artificial intelligence-related technologies?

A: Even for medical devices that use artificial intelligence technology, if the changes to be included in the change plan are not related to artificial intelligence technology, take actions according to Article 114-45-2, Paragraph 3, Item 1 of the Regulations.

No. 8. Documents required for confirmation application of change plans related to artificial intelligence-related technologies

Q52: (Column after change in the new/old comparison table)

In principle, the items to be described in each column of the application form for confirmation of a change plan should be presented in the form of a new/old comparison table for approval items before and after changes are made according to the change plan. Is it acceptable to describe (1) the contents to be described in the notification form at the time of notification and (2) what will be clearly described in the notification form at the time of notification as explanatory text if the contents to be described in the column after the change cannot be clearly described?

A: It is not acceptable. In the change plan, the contents of changes in approval items must be clearly stated before and after the change, and documents describing the improvement method to achieve the change, as well as the evaluation method to confirm that the improvement has been realized must be attached with appropriate performance targets.

Q53: (Preparation of attachments)

Section 3 of Notification by the Division Director "No. 3 Handling of documents to be attached to the application for confirmation of change plan and points to keep in mind when preparing them" states "Attached documents are (omitted) prepared in reference to the format of summary technical document (STED)." How should medical devices be prepared using artificial intelligence-related technologies?

A: Prepare by referring to Attachment 3.

Q54: (Submission documents specific to artificial intelligence-related technology)

In the case of medical devices using artificial intelligence-related technology, submission of "Procedures for preparation and implementation of the change plan" and "Other documents necessary for proper and smooth control of artificial intelligence-related technologies" is required in addition to documents related to Article 114-45-2, Paragraph 3, item 1 of the Regulations. Why do we need to submit these documents?

A: In the design and development of medical devices, the cycle of design, verification, and design improvement based on verification and justification of design improvements is performed. In the case of medical devices that use artificial intelligence-related technology, it is assumed that this process is performed continuously during additional learning, as in the development phase, and the submission of the procedures is required.

Q55: (Change plan for parts not related to artificial intelligence)

When a change plan is to be performed on parts not related to artificial intelligence technology for a medical device that uses artificial intelligence technology, is it acceptable to submit only the documents shown in Attached Table 1, instead of those in Attached Table 2 of the Director Notification?

A: For medical devices for which the change plan can be confirmed by the documents shown in Attached Table 1 of the Director Notification (including medical devices using artificial intelligence-related technology), it is acceptable to attach the documents shown in Attached Table 1 of the Director Notification as part of the application for confirmation of the change plan.

Q56: (Document on responsibility and authority for preparation and implementation of the change plan)

For the "Document on responsibility and authority for preparation and implementation of the change plan (*something like the organization chart)" shown in Table 2-b-1 of the Director Notification, what specific documents need to be submitted? Is it acceptable to refer to internal regulations related to QMS roles and responsibilities?

A: When a change is implemented by a commercial manufacturer, in-house rules and the organization chart of the QMS are considered. In the case of joint research and development with external institutions, written procedures, contracts, etc., in accordance with the procedures related to design and development, which clearly state the allocation of responsibility with joint research partners, must be presented.

Q57: (Procedure for implementation of the change of the change plan)

What specific documents need to be submitted regarding the "procedures necessary to implement the preparation, verification, validation, justification of the change plan, and changes to the change plan" indicated in b-2 of Attached Table 2 of the Director Notification (*Some procedures may be substituted by those related to design and development of QMS)? For example, can the procedures related to design and development themselves be replaced by these procedures?

A: If the QMS documents include the procedures necessary for review, verification, and justification, the QMS documents or documents that provide an outline of the QMS documents may be applicable. If post-marketing changes are made based on procedures similar to those for design- and development-related procedures, they can also serve as alternatives.

Q58: (Procedure for implementation of the change plan)

What documents need to be submitted specifically for the "procedure necessary to confirm that changes as indicated in the change plan have been implemented" shown in the Attached table 2-b-3 of the Director Notification?

A: It is necessary to show the procedure for confirming that the change has been implemented, as shown in the change plan, in the same way as the justification of improvement conducted during design development before the approval application.

Q59: (Post-marketing performance change control procedure)

It is required to attach "procedures necessary to control the performance of medical devices whose performance is expected to change after marketing" as a document corresponding to "Other documents necessary for proper and smooth control of

artificial intelligence-related technologies" shown in Attached Table 2-b of the Director Notification. What is specifically referred to here?

A: The term refers to the procedure used to control factors affecting the performance of the medical device. For example, procedures for the acquisition and selection of data to be used for additional learning, including validation, learning methods, test implementation methods, and the acquisition of data for performance evaluation, are considered. The factors to be controlled should be considered depending on the product.

No. 9. Handling changes according to the change plan associated with artificial intelligence-related technologies

Q60: (Change of medical institutions from which learning data are collected)

If it becomes necessary to change the medical institution from which learning data are collected after receiving confirmation of the change plan, is it necessary to submit a change plan change confirmation application?

A: Because the change may correspond to a minor change notification in the change plan, please consult the Office of Medical Devices, PMDA.

Q61: (Cases of refusal of confirmation of change plan)

Article 114-45-4, Paragraph 2, Item 4 of the Regulations stipulates that “changes that may impose significant impacts on the quality, efficacy, and safety of the medical device” should be regarded as cases in which change plans cannot be confirmed for medical devices utilizing artificial intelligence-related technologies. What is the specific definition of “significant impacts”?

A: An application for partial change should be submitted for medical devices utilizing artificial intelligence-related technologies if there is any change that may have a significant impact on the quality, efficacy, or safety of the medical device, such as a change in performance due to post-marketing learning, such as a change in clinical positioning, intended use, or effect. However, since items affecting the quality, efficacy, and safety of each product are different, it should be confirmed to consult the Office of Medical Devices, PMDA whether there is a possibility that the change plan may fall under the category of refusal of confirmation.

No. 10. Application for confirmation of change plans related to program medical devices

Q62: (Example of a description of program medical devices)

Please provide concrete examples of forms for application forms and attached documents of change plans necessary for program medical devices.

A: Refer to Appendix 1 and Appendix 2 for examples of the descriptions in IDATEN. These examples were prepared in accordance with the notifications, etc. issued by September 2023. When making an application for the confirmation of medical device change plans, the application form must be prepared in accordance with the latest notifications. It should also be noted that the examples of such descriptions were based on "Description Examples of Application Forms and Attachments for Marketing Approval (Certification) for Medical Device Programs" (Administrative Notice of the Office of Counselor for Medical Devices and Regenerative Medical Products, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated February 10, 2015). The "radiation therapy planning program" cited in the examples has established certification criteria and may not fall under the category of approval by the Minister of Health, Labour and Welfare.

Q63: (Acceptability of testing before completion of confirmation of the change plan)

Is it acceptable to perform tests based on the change plan without waiting for the completion of confirmation from the application for confirmation of the change plan in the change plan confirmation procedure system?

A: If the protocol, such as the implementation procedure of the change plan, is not expected to change, it is possible to implement the test without waiting for the completion of confirmation, at the responsibility of the commercial manufacturer of the medical devices. If any change is made to the protocol, such as the procedure for implementing the change plan as a result of the confirmation application, appropriate procedures, including retesting, must be followed.

Q64: (Multiple functions)

For programmed medical devices with multiple functions, can multiple changes be described for each function?

A: Yes. However, if more than one change is included in a single application for confirmation of the change plan, summarize the documents for application for confirmation of the change plan to ensure that the relationship between each change is clear.

Q65: (Retention of Records)

What records, traces, and evidence are required to be provided, including efficacy, safety, validation content, and other relevant details when a program medical device is updated according to a change plan?

A: Records shall be prepared and retained in a manner that complies with the requirements of the QMS Ministerial Ordinance and the company’s design and development procedures.

Attachment 1

(Example) Attachment to the application form for confirmation of a change plan

Number	Changed part										
	Date of approval (Date of notification)	Category	Name	Intended use or effects	Shape, structure, and principle	Raw materials	Standards related to performance and safety	Instructions for Use	Storage method and expiration date	Manufacturing method	Manufacturing plants for manufactured and sold items
1	Approval MM, YYYY	-	-	-	-	-	-	-	-	-	-
2	Approval of the partial change MM DD, YYYY	-	-	○	○	○	○	○	-	-	-
3	This time Application for confirmation of the change plan	-	-	-	Change (1)	Change (2)	Change (1)	-	-	-	-

○: Changed
●: Change plan item

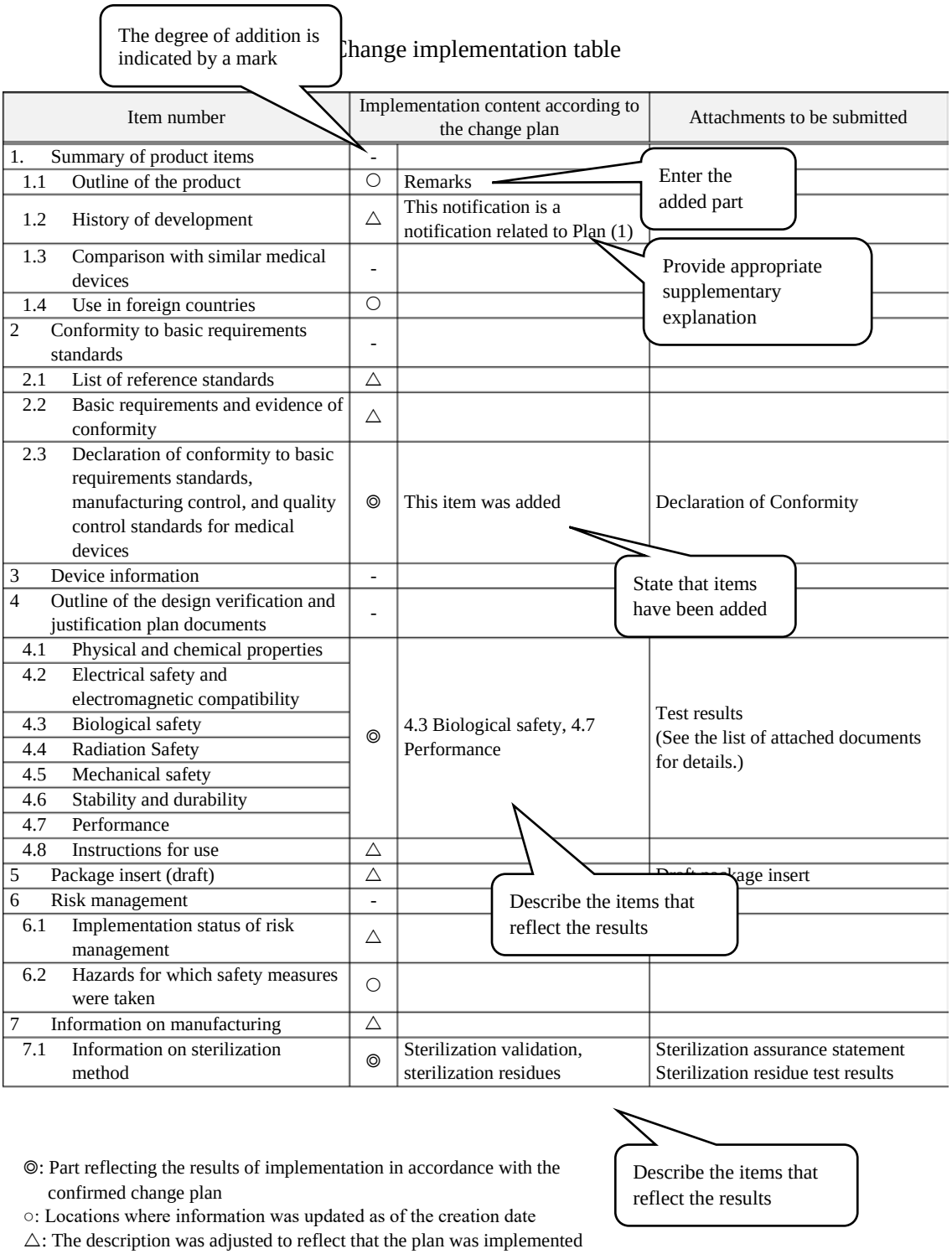
(Example of description) Attachment of the notification form related to changes according to the change plan.

Number	Changed part										
	Date of approval (Date of notification)	Category	Name	Intended use or effects	Shape, structure, and principle	Raw materials	Standards related to performance and safety	Instructions for Use	Storage method and expiration date	Manufacturing method	Manufacturing plants for manufactured and sold items
1	Approval MM, YYYY	-	-	-	-	-	-	-	-	-	-
2	Approval of the partial change MM DD, YYYY	-	-	○	○	○	○	○	-	-	-
3	Confirmation of the change plan MM DD, YYYY	-	-	-	Change (1)	Change (2)	Change (1)	-	-	-	-
4	Per change plan Notification of changes MM DD, YYYY	-	-	-	○ Change (1)	-	○ Change (1)	-	-	-	-
5	This time Notification of changes according to the change plan	-	-	-	-	○ Change (2)	-	-	-	-	-

○: Changed
●: Change plan item

Attachment 2

(Example of description) Change implementation table



Item number		Implementation content according to the change plan	Attachments to be submitted
1. Summary of product items	-		
1.1 Outline of the product	○	Remarks	
1.2 History of development	△	This notification is a notification related to Plan (1)	
1.3 Comparison with similar medical devices	-		
1.4 Use in foreign countries	○		
2 Conformity to basic requirements standards	-		
2.1 List of reference standards	△		
2.2 Basic requirements and evidence of conformity	△		
2.3 Declaration of conformity to basic requirements standards, manufacturing control, and quality control standards for medical devices	◎	This item was added	Declaration of Conformity
3 Device information	-		
4 Outline of the design verification and justification plan documents	-		
4.1 Physical and chemical properties	◎	4.3 Biological safety, 4.7 Performance	Test results (See the list of attached documents for details.)
4.2 Electrical safety and electromagnetic compatibility			
4.3 Biological safety			
4.4 Radiation Safety			
4.5 Mechanical safety			
4.6 Stability and durability			
4.7 Performance			
4.8 Instructions for use	△		
5 Package insert (draft)	△		Draft package insert
6 Risk management	-		
6.1 Implementation status of risk management	△		
6.2 Hazards for which safety measures were taken	○		
7 Information on manufacturing	△		
7.1 Information on sterilization method	◎	Sterilization validation, sterilization residues	Sterilization assurance statement Sterilization residue test results

◎: Part reflecting the results of implementation in accordance with the confirmed change plan
○: Locations where information was updated as of the creation date
△: The description was adjusted to reflect that the plan was implemented
-: No change from the time of the change plan application

Attachment 3

Documents to be attached to the application for confirmation of the change plan for the medical device

Attached Table	Attachments	Items in the attachments	
		Notification by the Division Director (Attached Table 1, Attached Table 2)	STED format
Attached Table 1 Items for documents to be attached to the application form for confirmation of the change plan (related to Article 114-45-2, Paragraph 3, Item 1 of the Regulations)	(b) Change plan	1. Documents on the background of development 2. Status of use in Japan and overseas	1. Summary of product items 1.1 Outline of the product 1.2 History of development 1.3 Comparison with similar medical devices 1.4 Use in foreign countries
		3. Documents related to the change plan	4. Summary of the design verification and justification documents
		4. An old/new comparison table	3. Device information
	b. Documents related to the design and development verification methods	1. Documents related to the protocol for the verification of changes in performance and safety. 2. Other documents related to the design verification protocol	4. Summary of the design verification and justification documents 2. Conformity to basic requirements standards
		3. Documents on plans related to risk management implementation 4. Documents related to the safety measures plan for the system	6. Risk management 6.1 Implementation status of risk management 6.2 Hazards for which safety measures were taken
		5. Documents related to plans for changes to manufacturing processes and plants 6. Documents related to the sterilization change plan	7. Information about the manufacturing process 7.1 Information about the sterilization method
		7. Documents related to the clinical study protocol 8. Documents on the clinical evaluation protocol	8. Clinical study test results, etc. 8.1 Clinical study results, etc.
		9. Documents related to the plan of post-marketing surveillance, etc.	9. Plan for post-marketing surveillance, etc.
		10. Documents related to package inserts	5. Package insert (draft)
Attached Table 2 Items for documents to be attached to the application form for confirmation of the change plan (related to Article 114-45-2, Paragraph 3, Item 2 of the Regulations)	(b) Procedure for preparation and implementation of the change plan	The following procedures are considered necessary to ensure the quality, efficacy, and safety of artificial intelligence-related technologies. 1. Documents describing the responsibilities and authorities for the preparation and implementation of the change plan (*something like organization chart)	4. Summary of the design verification and justification documents
		2. Procedures necessary for preparation, review, verification, justification of the change plan, and implementation of the change plan (*can be partially substituted by procedures related to design and development of QMS)	4. Summary of the design verification and justification documents
		3. Procedures necessary to confirm that the change indicated in the change plan has been implemented	4. The procedures for verifying matters applicable to a reliability inspection are shown.
	b. Other documents necessary for the proper and smooth control of artificial intelligence-related technologies	1. Other documents necessary for the proper and smooth control of artificial intelligence-related technologies Procedures for controlling the performance of medical devices whose performance is expected to change post-marketing	9. Plan for post-marketing surveillance, etc.