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Essential Principles and Content of Predetermined Change Control Plans

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Preface

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1. Introduction

Software has become an integral part of modern healthcare, driving transformative advancements in diagnostics, treatment, and patient management. A critical subset of this technology is medical device software which meets the definition of a medical device and is defined in *IMDRF's N81 Characterization Considerations for Medical Device Software and Software-Specific Risk*. Given its critical role in patient care, medical device software is subject to rigorous regulatory oversight to ensure it consistently meets high standards of safety and performance.

While patients benefit immensely from timely access to medical device technologies, the rapid pace of software development presents a challenge for traditional regulatory processes, which can lead to delays in deploying important updates, thereby hindering patient access. As with most software applications, medical device software may benefit from frequent updates to improve functionality, address real world use, and respond to evolving clinical environments. A Predetermined Change Control Plan (PCCP) allows manufacturers to seek authorization to implement planned changes to ensure the continued safety and effectiveness of their medical device software. A PCCP is appropriate for certain changes that would otherwise be subject to regulatory authorization prior to implementation.

A PCCP describes a plan, proposed by a manufacturer, that states:

1. the specific planned changes to the medical device software,
2. the change plan/protocol for implementing and controlling those changes with predefined acceptance criteria/pre-specified performance criteria, and
3. the assessment of impacts from those changes.

This approach allows for more rapid adaptation of software, faster access, and the ability to responsibly evolve in response to new data and technological advancements. By enabling the authorization of certain planned changes, PCCPs can help maintain the balance between innovation and regulatory oversight without compromising patient safety.

The adoption of PCCPs offers numerous benefits. For patients, the authorization of PCCPs may support quicker access to improved medical device software, which can lead to better health outcomes. For healthcare systems, PCCPs can enhance operational efficiency through the continuous improvement of products. For manufacturers and regulators PCCPs can increase administrative efficiency, streamlining the regulatory process by reducing the burden of multiple regulatory submissions. In doing so, manufacturers may improve their planning and accelerate time-to-market for updates while maintaining the safety and effectiveness of the medical device software. On a broader scale, PCCPs promote early interaction and collaboration between manufacturers and regulatory authorities.

Despite the benefits, there are also some challenges to overcome. Regulators will face an increased submission complexity at the time of the initial regulatory review. This complexity also applies to manufacturers, who will need to prepare the necessary documentation for PCCPs at the time of submission. Clear documentation and communication between manufacturers and regulatory authorities is crucial to ensure traceability and implementation around the acceleration of modifications of medical device software within the context of a robust quality management system. Additionally, manufacturers should be cognizant of the differences in jurisdictional adoption of PCCPs as this may complicate their PCCP authorization plans and/or their global reliance strategies.

PCCPs have the potential to be applied beyond medical device software to other areas of medical technology. The evolution of PCCPs could lead to more flexible and responsive regulatory frameworks, better suited to the fast-paced nature of technological innovation in healthcare. However, the focus of this document is on medical device software.

Given the emerging nature of PCCPs at the time of this publication, their implementation may vary across different regulatory jurisdictions. This document serves to facilitate international convergence and harmonize approaches across jurisdictions by describing essential principles for PCCPs.

Throughout this document, the terms “change” and “modification” are used interchangeably. Additionally, the term “user” refers to the intended healthcare professionals and/or patients who interact with the medical device software. Ensuring patient safety and meeting patients’ needs is paramount in the development and regulation of these technologies.

2. Scope

2.1 Purpose of the document

The purpose of this document is to share high-level principles on the use of PCCPs as a way of authorizing certain planned medical device software modifications for which regulatory authorization is otherwise required. Additionally, it aims to identify the elements that manufacturers should consider when developing and documenting a PCCP to support regulatory review. The document outlines a broad, but harmonized framework for PCCPs, allowing each jurisdiction to apply the concepts within the scope of regulations applicable to their jurisdiction.

This document is intended to:

1. Identify essential principles for developing a PCCP for medical device software;
2. Establish the elements of a PCCP for modifications to medical device software;
3. Highlight the scope of changes that could be considered within the bounds of a PCCP; and
4. Highlight the benefits and challenges of PCCPs for patients, healthcare professionals, users, regulators, and manufacturers.

2.2 Scope of the document

This document applies to the subset of software that meets the definition of a medical device (referred to throughout as medical device software), including Software as a Medical Device (SaMD) as defined in *IMDRF SaMD WG N10 Software as a Medical Device: Key Definitions*.

1. This document is not intended to be an interpretation or replacement of any jurisdiction's laws and regulations.
2. This document aims to support international convergence on the high-level principles of PCCPs to support their long-term utility as the concept is leveraged or referenced across jurisdictions.
3. This document focuses on best practices that manufacturers should consider when developing PCCPs.
4. This document is not intended to define specific types of changes acceptable for inclusion in a PCCP or to establish regulatory requirements for a PCCP.
5. The content in this document is not regulation or guidance regarding PCCPs or similar plans across jurisdictions. Additional work may be required to apply and align these concepts in a given jurisdiction. Furthermore, not all jurisdictions may be accepting PCCPs or similar plans for review.

3. References

1. *IMDRF SaMD WG N10 FINAL:2013 Software as a Medical Device: Key Definitions*
2. *IMDRF SaMD WG N81 FINAL:2025 Characterization Considerations for Medical Device Software and Software-Specific Risk*
3. *IMDRF/RPS WG/N9 FINAL:2024 (Edition 4) Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)*

4. Essential Principles

Robust PCCPs, including those for medical device software, encompass the foundational concepts outlined below.

1. **Focused and bounded**: A PCCP describes the changes that a manufacturer intends to implement with enough specificity to ensure the continued safety and effectiveness of the medical device software. Such changes are limited to modifications within the intended use or intended purpose of the original medical device software.

2. **Risk-based**: The value and reliability of a PCCP are strengthened when the intent, design, and implementation of a PCCP are driven by a risk-based approach. This approach adheres to the principles of risk management to ensure that risks are adequately managed and controlled and should be integrated within an existing risk management framework.

3. **Evidence-based**: Evidence generated throughout the Total Product Lifecycle (TPLC) of the medical device software with a PCCP is important to ensure the ongoing safety and effectiveness of the medical device software and that the benefits outweigh the associated risks.

4. **Transparent**: For PCCPs, the best practice is to provide clear, meaningful, timely, and appropriate transparency to intended users consistent with the authorized PCCP for the medical device software. This helps ensure that intended users remain aware of the medical device software's performance and use before and after changes are implemented. Manufacturers should also provide relevant and robust information in the PCCP to ensure regulators can make an informed decision regarding the continued safety and effectiveness of the medical device software with a PCCP.

5. **TPLC**: Creating and using a PCCP from a TPLC perspective can elevate the quality and integrity of a PCCP by continually considering the perspectives of all intended users, availability of new data, and risk management practices throughout the TPLC. The use and support of established regulatory, quality, and risk management frameworks throughout the TPLC will help strengthen device safety.

5. Fundamentals of a PCCP

A PCCP is an optional mechanism for manufacturers to convey planned changes in their submissions to regulatory authorities to support a marketing authorization of a device. PCCPs may be utilized to support iterative and planned improvements to a device, while improving or ensuring continued safety and effectiveness. The PCCP should be developed and managed within the manufacturer's existing quality management system, including the risk management process. Changes included in a PCCP are limited to changes *within* the medical device software's original intended use or intended purpose.[1]

A manufacturer's quality management system, specifically the risk management and change management processes, is critical to ensure that medical device software consistently meet applicable regulatory requirements and predefined specifications. This is particularly important for medical device software that is authorized with a PCCP, as PCCPs include changes that would otherwise require a new marketing submission. Device changes authorized via a PCCP within a regulatory submission are expected to be implemented according to the manufacturer's quality system, particularly the risk management processes, and in line with existing regulatory requirements.

Version control for a PCCP is important to ensure that regulators and manufacturers clearly understand the final authorized version of a PCCP. This is also important when a manufacturer wishes to make modifications to a previously authorized PCCP, so that new authorized versions can be adequately tracked. To promote adequate traceability within a given PCCP, it can also be useful for the manufacturer to connect each change proposed to a specific verification and/or validation plan in the PCCP. This may help regulators to more easily identify where comprehensive information about each change is located as well as how the proposed changes may affect the medical device's safety and performance, if applicable.

5.1 Elements of a PCCP

Together, the elements of a well-formulated PCCP clearly capture the changes a manufacturer plans to make to its authorized medical device software, and how those changes will be made in a structured manner to ensure that the medical device software's safety, effectiveness and proper use will be maintained.

While the changes included in the PCCP may be interconnected or independent from each other, manufacturers are encouraged to provide an analysis of the anticipated benefits and risks of implementing the PCCP, in part or in whole, to ensure that the benefits of implementing the PCCP will outweigh the risks.

[1] For example, model updates using newer data to expand the subset of an existing patient population may be appropriate for inclusion in a PCCP, provided these changes fall within the original intended purpose.

Generally, a PCCP consists of a detailed Description of Changes, a Change Plan, and an Impact Assessment, as these elements are intended to provide the given regulatory authorities with comprehensive information that will enable a detailed review of the proposed changes, along with other required documentation.

1. The **Description of Changes** details the changes that a manufacturer plans to make to the medical device software and a justification for how these changes will ensure the continued safety and effectiveness of the device.

2. The **Change Plan** supports each change detailed in the Description of Changes and describes the verification and validation activities, including pre-defined acceptance criteria, how the changes will be deployed, and how the changes will be communicated to intended users.

3. The **Impact Assessment** links the Description of Changes to the Change Plan, by evaluating the impact of the changes, including the anticipated benefits, risks, and mitigations of the risks introduced by the changes. It addresses how the activities described in the Change Plan will continue to assure the safety, effectiveness, and proper use of a device as changes are deployed. As such, the elements of a PCCP are interconnected.

A description of the elements is provided below.

5.1.1 Description of Changes

A dedicated Description of Changes section in a PCCP identifies the planned changes to the medical device software that the manufacturer intends to implement with enough specificity to assess the continued safety and effectiveness of the device. This section details the list of individual proposed device changes discussed in the PCCP, as well as the specific rationale for each change. This section also includes details on specifications of the characteristics and performance of the device that can be verified, validated, and deployed.

To promote traceability, it can be useful for each change proposed by the manufacturer to be connected to specific verification and validation plan or protocols within the Change Plan. Importantly, because a robust PCCP includes only select changes that can be verified, validated, and deployed, manufacturers should clearly establish boundaries that define the range of the proposed changes to the medical device software in their PCCP.

The Description of Changes is also the section of the PCCP where the implementation of the proposed changes can be specified. For example, a Description of Changes is where a manufacturer may specify if the proposed changes in a PCCP will be implemented in a uniform manner across all devices on the market (sometimes referred to as homogenous or global changes, or global adaptations), and/or implemented differently for different devices on the market. The implementation may be based on the unique characteristics of a specific clinical site or individual patients (sometimes referred to as heterogenous or local changes, or local adaptations). In addition, manufacturers can include information regarding the expected frequency of updates, if known.

Where applicable, the Description of Changes is where a manufacturer specifies if a proposed change will be implemented automatically (i.e., whether the changes are implemented automatically by software), manually, (i.e., involving steps that require user, manufacturer, healthcare provider, or patient input, action, review, and/or decision-making), or a combination of both.

5.1.2 Change Plan

The primary goals of the Change Plan are to:

1. identify the performance evaluation methods, i.e., the appropriate and applicable data, test and evaluation methods, analysis methods, and specified acceptance criteria that will be used to verify and validate the modifications, and

2. identify the update procedures, i.e., the process to deploy proposed changes mapped out in the Description of Changes and the plan to communicate these changes to different end users, as needed.

Performance Evaluation Methods: Performance evaluation of the medical device software is important to ensure that the current medical device software performance and the pre-specified acceptance criteria for all proposed changes will continue to be met. Thoroughly presented performance evaluation methods generally include the plans to verify and validate that the changed medical device software will meet the specifications identified as part of a specific change, in addition to maintaining the requirements that are not part of the change but may be impacted by the change.

Performance evaluation may also include, as applicable, the plans for verification and validation testing of the medical device software following the implementation of each individual change, and in aggregate. Specifically, the Change Plan may provide, as applicable, details on the implemented changes, including:

- a summary of the current medical device software performance
- a description of the relevant data used to implement a change
- associated inputs/outputs
- performance metrics
- pre-defined acceptance criteria
- statistical tests for each planned change, and
- related evidence to support authorization of a PCCP.

A robust Change Plan also includes information about how a manufacturer intends to document and address any failures in the performance evaluation for a specific change. The Change Plan is expected to document how the failure(s) will be recorded, as well as a mechanism for assuring the specific change(s) will not be implemented if they cannot meet predefined acceptance criteria per the methods specified in the Change Plan.

Update Procedures: The update process specifies how the manufacturer will deploy proposed changes mapped out in the Description of Changes and the plan to communicate the implemented changes to intended users, as needed. It is important for the manufacturer to identify, as appropriate, in the update procedure a description of the communication and/or training applicable to intended users for the implemented change. The Change Plan may include appropriate labelling update plans, post-market surveillance plans and procedures (such as real-world monitoring), and notification requirements. This information is provided to users, as applicable, should the medical device software not function as intended after implementation.

It is important for a manufacturer to ensure that the update procedures address, as appropriate, how labelling will be updated when changes are implemented to ensure clear information is provided to users when they need it. It is also important to include a description of the labelling sections that are anticipated to be impacted by the implementation of the proposed changes. Note that different types of changes may warrant different types or timings of notifications (e.g. minor software release notification vs. advanced warning for major changes that may have operational impact). For marketed devices labelling provided to intended users must reflect information about the current version(s) of the device available. To minimize confusion about the marketed version(s) of the medical device software, information on changes to the medical device software that may have been included in a PCCP-based authorization but have not yet been implemented, should generally *not* be included in available labelling.

5.1.3 Impact Assessment

The Impact Assessment is the evaluation of the anticipated benefits and risks of implementing the individual and cumulative changes outlined in the PCCP for a medical device software, as well as the mitigations for those risks. The Impact Assessment provides assurance that the proposed changes in a PCCP are unlikely to introduce additional, unmitigated risks and that the safety and effectiveness of the medical device software as a whole are maintained or improved when the changes are implemented. Notably, the Impact Assessment includes additional considerations (e.g., cumulative impact of implementing all changes) to the typical risk assessment that is meant to support the risk management activities for the medical device software. The manufacturer's existing quality system should serve as the framework for conducting an Impact Assessment for the modifications set forth in the PCCP.

Manufacturers may consider the following when developing the Impact Assessment within a PCCP:

1. Comparison of the version of the medical device software with each change implemented individually against the version of the medical device software without any changes implemented;

2. Discussion of the anticipated benefits and risks, for example, potential risks of harm and unintended bias with AI devices, of each individual change – this should also include any anticipated benefits and risks introduced by the process of changing the medical device software in the post-market phase after the device has been deployed;

3. Discussion of how the methods described in the Change Plan will maintain the medical device software's safety and effectiveness;

4. Discussion of how the implementation of each change may impact other planned changes, as applicable; and

5. A description of the cumulative impact of implementing all changes, where possible.

6. Benefits and Challenges of PCCPs

6.1 Benefits of PCCPs

Innovations in medical device software are transforming healthcare by improving diagnostics, treatment, and patient monitoring. When appropriately utilized, PCCPs allow for authorized, well-documented modifications to occur after the medical device software has been placed on the market, enabling patients and healthcare systems to benefit from accelerated access to innovation while regulators and manufacturers maintain regulatory compliance and device safety.

6.1.1 Better health outcomes for patients

One of the key health benefits of PCCPs is that they give patients quicker access to enhancements in medical device software. Under PCCPs, certain innovations can progress expeditiously, enabling the efficient implementation of authorized changes to marketed medical device software. Timely access ensures that patients can benefit from the latest advancements in medical technology, ultimately leading to better health outcomes and more effective treatments for patients.

PCCPs support the incorporation of new clinical evidence, ensuring clinicians have reliable medical device software to deliver accurate and appropriate care. This not only can reduce the risk of errors but also may lead to better clinical outcomes, building trust in the medical device software's safety and effectiveness. That trust supports confident decision-making and reassures patients that they are receiving timely, reliable, and high-quality care.

By supporting a proactive and flexible update process, PCCPs can enable manufacturers to respond swiftly to real-world use, ensuring patients have timely access to technological advancements.

For regulatory authorities, PCCPs can simplify processes by reducing the need to review medical device software changes as separate submissions. They can also provide regulators with deeper insights into expected market developments and can support horizon scanning efforts. For patients, this means potential safety and compliance issues can be identified and addressed more swiftly, keeping patient safety at the forefront and ensuring more reliable and up-to-date medical device software.

6.1.2 Enhanced operational efficiency across healthcare systems

PCCPs support forward-planning of improvements to medical device software based on authorization of planned changes. These modifications can be scheduled and deployed to minimize disruption to clinical workflows, reducing downtime and potential risks to patients. Additionally, PCCPs could provide a streamlined mechanism for deploying updates in a predetermined timeframe thereby improving response time and risk mitigation.

PCCPs align well with the evolving nature of modern healthcare systems by supporting adaptive software – systems that can learn from new data, incorporate clinical updates, and adjust their performance over time. This adaptability is essential in dynamic care environments, where rapid changes in evidence, patient populations, and technologies demand flexible solutions. By enabling well-planned, quicker, and more efficient updates, PCCPs can facilitate the delivery of medical device software that is frequently improved, more responsive to clinical needs, and increasingly tailored for individual patients.

6.1.3 Increased administrative efficiency

Over the lifetime of the product, the administrative efficiency that results from using PCCPs can lead to continuous improvements that enable patients or users to receive more precise and adaptive care, improving treatment accuracy and effectiveness.

Advancements in medical device software's over time have the potential to enhance the quality of healthcare and treatment more efficiently. A reduced administrative burden such as the time required for new or improved versions of medical device software to reach the market, may positively impact patients and/or users.

Over a medical device software's total product lifecycle, PCCPs can support an agile, compliant, and safety-conscious approach to development and enhancement, fostering continuous innovation without compromising regulatory standards. PCCPs can also be an efficient mechanism to support planned changes to a medical device that are implemented repeatedly.

By extension, any efficiency gains achieved by manufacturers and regulators may allow scarce resources to be allocated toward other regulatory activities and submission reviews. PCCPs enable regulators to authorize specific modifications to medical device software, thereby eliminating the need for multiple subsequent submissions for each change. This process optimizes the authorization timeline conserving resources for both regulators and manufacturers. For manufacturers, this flexibility may allow for the consideration of new methodologies and modifications that were previously deprioritized due to high costs.

Furthermore, evaluating potential modifications may encourage an increase in initial interactions between manufacturers and regulators, ensuring both parties are aligned with the planned modifications early in the product lifecycle.

The potential benefits of PCCPs are considerable. PCCPs can drive innovation, aligning with the goal of every regulatory body to balance advancements in patient care within their respective countries or jurisdictions with strict regulatory compliance. Additionally, PCCPs can provide a structured yet flexible framework that can adapt to the rapid pace of technological advancements in the medical device industry, ultimately resulting in a positive impact for patients.

6.2 Challenges of PCCPs

In addition to the risks associated with modifying medical device software, PCCPs can introduce further challenges.

Distinct challenges of PCCPs include:

- more complex submissions for manufacturers,

- more complex submissions for regulators to review and authorize,
- traceability and implementation,
- varying levels of PCCP adoption internationally and added reliance complexities.

6.2.1 Submissions that include PCCPs

Submissions with PCCPs will require additional preparation time due to the need for extensive evidence gathering and documentation creation compared to a traditional submission. This can increase preparation time for manufacturers, raise initial costs, and extend the duration between preparation of a submission and a submission reaching the appropriate regulatory authority, potentially increasing the time-to-market and return on investment. This may present a challenge for smaller manufacturers, given the initial resource investment required and the necessity for sourcing expertise and experience to gather sufficient evidence.

6.2.2 PCCP review and authorization

Certain jurisdictions have statutory requirements for reviewing a submission within a specific time period, regardless of whether a PCCP is included. The PCCP is an additional component of a submission which can require that additional resources be allocated for the regulatory review. The increasing complexity of PCCPs may be challenging while regulators become familiar with new proposals, such as those involving site-specific changes. Other jurisdictions could have different review timelines and authorization processes due to the inclusion of a PCCP.

In general, from a regulator's perspective, the inclusion of a PCCP and its proposed modifications can introduce a more complex assessment process. Focusing a PCCP on a limited number of proposed changes can be a helpful approach to ensure that regulators are reasonably able to review the PCCP. Although there may be some added complexity in the submission, the benefits of overall efficiency are realized later in the medical device software lifecycle.

6.2.3 Traceability and implementation

PCCPs can redistribute risks across the lifecycle by introducing a more stepwise and adaptable approach to product development and maintenance. This requires robust traceability mechanisms and comprehensive risk management frameworks to safeguard the integrity and functionality of the medical device software, posing a significant challenge to both manufacturers and regulators.

PCCPs must be monitored for the extent of cumulative changes and there should be assurance that the evolving evidence base continues to support the intended purpose and risk profile of the medical device software. Manufacturers will need to ensure that PCCPs are managed within a robust quality management system to ensure that there is accountability and so that implemented changes are appropriately documented and communicated.

6.2.4 International alignment and recognition

Not all jurisdictions may accept PCCPs or similar plans for review at this time. For those that do, the nuanced differences between regulatory jurisdictions have the potential to complicate a PCCP designed for use in multiple jurisdictions. For example, a modification considered low risk and within the intended purpose in one region may exceed risk thresholds or fall outside the PCCP framework in another jurisdiction. Although the intention of this document is to harmonize the approach for PCCPs across jurisdictions, manufacturers should be aware of jurisdictional differences in implementation. Additionally, some jurisdictions utilize self-certification routes to regulatory conformity. It is the responsibility of manufacturers to ensure any existing or planned PCCPs are compatible with such routes when accounting for international alignment.

Jurisdictions that have a reliance mechanism, will need to consider PCCPs in a reliance framework alongside jurisdictional differences which may impact factors such as generalizability, acceptable standards and evidence requirements. Harmonization in reliance will need to be established. Ultimately it is the responsibility of manufacturers to ensure that all factors relevant to jurisdictional differences are addressed when they use a reliance mechanism to apply for marketing authorization.

7. Conclusion

Patients can benefit when medical device software is able to advance in a timely manner through regular updates and thoughtfully planned changes. Medical device software changes can be helpful to potentially address real world use or adapt to changing healthcare environments. A PCCP is one way, in certain jurisdictions, manufacturers can gain authorization to make planned updates to their medical device software before they are implemented, while providing assurance that their devices will remain safe and effective. While taking a PCCP approach to managing changes to medical device software relies on manufacturers and regulators to invest in robust engagement and creating specific, mature modification plans early in a device's lifecycle, a PCCP can enable patients to further benefit from timely access to high quality medical device software and provide manufacturers with the flexibility to deploy changes to these devices in a manner tailored to their needs. This document highlights essential principles for the PCCP approach and serves to facilitate international convergence and harmonized approaches across jurisdictions to harness medical device software advancements.

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