TGA Approach to Predetermined Change Control Plans

Purpose

This is a technical guidance intended for manufacturers, developers and sponsors of medical device software. This guidance has been developed to outline how predetermined change control plans (PCCPs) can be used to gain premarket regulatory approval to implement a change at a future stage. This draft guidance applies to medical device software, including software as a medical device (SaMD), software embedded in, or driving, other devices and in vitro diagnostic (IVD) software. It is particularly relevant to artificial intelligence or machine learning (AI/ML) enabled medical device software that is updated iteratively or where the model is re-trained.

PCCPs address software changes the manufacturer plans to make after obtaining pre-authorisation from the Therapeutic Goods Administration (TGA) or a comparable overseas regulator. PCCPs have defined boundaries for allowable changes, whereby the manufacturer can pre-specify verification and validation methods and acceptance criteria.

Introduction

The TGA helped develop the 2025 International Medical Device Regulators Forum (IMDRF) draft guidance document *'Essential Principles and Content of Predetermined Change Control Plans'*: www.imdrf.org/consultations/essential-principles-and-content-predetermined-change-control-plans. This draft TGA guidance aligns with the IMDRF document.

A manufacturer may use a PCCP to seek pre-authorisation of substantial changes under their TGA conformity assessment certification, or to support a sponsor's application to include or vary a medical device on the Australian Register of Therapeutic Goods (ARTG). Once we (the TGA) approve, the manufacturer can then implement the PCCP for devices in Australia.

A PCCP is appropriate for certain planned changes that would otherwise require regulatory authorisation prior to implementation each time any of the changes were made (for example, for repeated software updates). With a TGA approved PCCP, the manufacturer and sponsor would not need further pre-market assessment or authorisation by us. However, sponsors would still need to meet any other Australian regulatory requirements that may apply.

A PCCP is a manufacturer's plan that describes:

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

A PCCP allows manufacturers to more rapidly update their software, with faster access for users and patients, and to responsibly evolve their software in response to new data and technology. PCCPs can help balance innovation and regulatory oversight without compromising patient safety.

PCCPs do not remove the need for clinical evidence or for verification and validation to be performed and documented. PCCPs may affect how, when, and if we review the clinical evidence or the verification and validation results, according to risk.

PCCPs are relevant where changes would otherwise trigger regulatory submission or assessment. Manufacturers would therefore normally only use a PCCP for higher risk-class software that requires our approval, and PCCPs would normally not be needed for exempt medical device software or for Class I medical device software, unless it has a measuring function.

Changes that can be covered by a PCCP

PCCPs are most suitable for predictable, well-characterised changes and must only be used for changes that are explicitly described in the approved PCCP. A PCCP may only include changes that do not change the original intended purpose of the medical device, and with pre-specified verification, validation and acceptance criteria, such as:

- pre-specified AI/ML model re-training within defined data characteristics, performance floors, drift monitoring triggers, and acceptance criteria
- integration with a new input data source or system interface (e.g. a new file format, data feed, or interoperability update) where the intended purpose is unchanged and predefined acceptance criteria confirm performance is maintained
- pre-specified update to an IVD software algorithm parameter set within defined limits, with fixed clinical decision thresholds and documented verification and validation requirements
- pre-specified user interface update that does not change clinical output or decision logic, with usability verification and regression testing defined in advance
- planned maintenance updates (e.g. planned dependency, third party software, software of unknown provenance, or operating system compatibility updates) where the change boundaries, verification and validation, and acceptance criteria are pre-specified and the intended purpose remains unchanged.

Changes that cannot be covered by a PCCP

Some types of changes must not be managed in a PCCP. Those changes should be managed through standard change control or post-market compliance actions, or premarket variation applications, as necessary. Refer to Device Change Request and variations and Recalls and other market actions for more information.

Changes that cannot be covered by a PCCP include:

- changes to the medical device software's original intended purpose
- broad, open-ended changes such as 'future improvements'
- changes to safety-critical attributes such as changes that alter clinical decision logic, alarm or alert behaviour, fail-safe behaviour, or other controls relied upon to manage serious risk
- non-software changes (e.g. material or hardware changes) must use other regulatory pathways - a PCCP can only cover software changes
- unanticipated changes triggered by safety signals, complaints, cyber security events, corrective actions, field feedback, post-market surveillance, or real-world performance issues, where the change is reactive in nature and not explicitly pre-defined within the PCCP.

Applying for a Conformity Assessment Certificate

Where a manufacturer applies for a conformity assessment certificate and includes a proposed PCCP, we will assess the PCCP in the context of assessing the manufacturer's change control under its quality management system. A manufacturer may propose a PCCP after initial certification where the change is within the scope of the certificate, using a substantial change application.

The PCCP should be consistent with specified criteria in the IMDRF guidance document.

If we are not satisfied with the PCCP (e.g. inadequate boundaries, acceptance criteria, impact assessment), we will request further information. If we remain unsatisfied we may proceed with a certification decision that refuses to accept the PCCP to address future software changes.

We will inform the manufacturer in writing if we accept the PCCP and may specify the details in the certificate or its schedules.

When the manufacturer implements a substantial change to the software that is covered in an approved PCCP, they must notify us. We will record the notification without further assessment. This is a key benefit of PCCPs and is a faster pathway to implement planned change. For information on changes to conformity assessment certificates and how to notify us, see: Changing or transferring Conformity Assessment certificates | Therapeutic Goods Administration (TGA).

Applying with comparable overseas regulator certification

A sponsor may apply to us to include a software medical device on the ARTG supported by comparable overseas regulator evidence and include a PCCP that has been approved by the same comparable overseas regulator. We will not accept a PCCP approved by a different comparable overseas regulator than used to support the ARTG application.

A sponsor may also apply to vary ARTG information using the variation application process and include the PCCP with the application, with evidence that the comparable overseas regulator approved the PCCP. We will not accept a PCCP approved by a different comparable overseas regulator than used to support the ARTG entry.

If an application that includes a PCCP is selected for application audit or review, we will use the PCCP to inform that activity. However, for applications that are not selected for audit or review, we would normally not review the PCCP in detail.

Sponsors should:

- state in the application cover letter that a PCCP is in place for the product
- provide evidence that the PCCP has been approved by the relevant comparable overseas regulator
- provide a summary of how the PCCP applies to the software versions covered by the application
- identify whether the planned changes would require information in the ARTG to be updated and therefore trigger the need for a Device Change Request or Variation application
- state whether the changes trigger associated changes to Unique Device Identifiers (UDIs)
- provide PCCP version identification including the version approved by the comparable overseas regulator
- when submitting an updated PCCP, provide a redlined comparison, a summary of updates, and justification for unchanged sections.

Importantly, PCCPs do not substitute for Device Change Request or Variation requirements. Existing rules continue to determine whether a premarket application is required. A PCCP provides evidence that may support those pathways and allow them to be performed earlier, before the software changes have been verified and validated.

Evidence requirements for a PCCP

Regardless of the application pathway, the PCCP must describe the software changes and define:

- the variables that may change
- the limits of those changes
- what is explicitly excluded from the PCCP.

A proposed PCCP needs to demonstrate to the regulator that the manufacturer is capable of safely managing the changes. Including an unreasonably high number of changes or highly complex changes in a PCCP may reduce the regulator's confidence and the PCCP may not be accepted.

The PCCP should document the change at a similar level of detail that would otherwise be provided in a regulatory submission for the device and the proposed change. Higher-risk products such as Class IIb/III SaMD, SaMD with AI, software that controls higher-risk devices, and IVD software would normally need more detailed documentation.

The key details to provide in a PCCP are:

1. A description of the specific planned changes to the medical device software, including but not limited to:
    a. the objective or reason for the change
    b. any change to device performance or characteristics
    c. changes to labelling
    d. whether the change will be automatic or manual
    e. if it affects all models of the device or just one site or region.

2. The change plan or protocol for implementing and controlling the changes with predefined acceptance criteria and pre-specified performance criteria, including but not limited to:
    a. the predefined verification and validation methods
    b. data requirements and management processes
    c. pre-defined acceptance criteria that are quantitative, statistically sound, risk appropriate, and clinically meaningful
    d. change communication process
    e. user training (where appropriate)
    f. labelling updates (where appropriate).

    The elements of the change plan or protocol should be explicitly linked to the planned change as detailed in the description.

    Where planned changes affect the user interface, workflow, or user interaction, the PCCP should include usability or human factors evaluation appropriate to the risk and the nature of the change.

3. An assessment of impacts of the changes, including but not limited to:
    a. a detailed risk assessment

b. demonstration that the proposed changes will not introduce new, unmitigated risks and that the safety and effectiveness of the device is maintained or improved
c. where appropriate, assessment of the impact on accessories or compatible devices
d. cybersecurity impact assessment, including whether the planned change affects exposure to unauthorised access or modification, dependencies on software of unknown provenance, or security controls
e. interoperability or interface testing expectations where planned changes affect inputs, data sources, or system interfaces.

Where relevant, the PCCP should describe how planned changes will be implemented (e.g. uniformly across all deployed instances versus site or patient-specific adaptations) and whether implementation is automatic, manual, or a combination, including the associated controls and traceability.

Where local adaptations are supported in an accepted PCCP, responsibility for compliance and release remains with the manufacturer, consistent with the approved PCCP.

The PCCP should also address the following:

Data representativeness or relevance to the Australian population:

- A rationale for why data used for retraining or validation remains relevant to Australian settings such as demographics, ethnicity, disease spectrum, clinical or imaging workflows, and device types used in Australia.
- Bias or equity assessment of subgroup performance and bias controls relevant to Australian populations, and justification that retraining or validation datasets remain representative over time.
- Traceability documentation sufficient to link data sources and pre-processing to performance outputs and acceptance decisions.

Cumulative drift management

- How the manufacturer monitors for cumulative changes and assures the evolving evidence base continues to support the intended purpose and risk profile over the total product lifecycle.
- How the manufacturer monitors post-market performance including a description of how real-world performance will be monitored, what signals or triggers initiate a planned modification, and how monitoring results feed into PCCP decision-making and user communications.

Transparency and user communication

- A clear description of how implemented changes are communicated to users, including training needs and labelling updates.
- Assurance that available labelling reflects the current marketed versions, with appropriate notice for changes that have operational impact.
- Labelling and user-facing materials should reflect implemented changes only and planned PCCP changes that have not yet been implemented should generally not be described as current device performance or functionality.

Unique Device Identifier (UDI) and PCCPs

Manufacturers must determine if the planned change will require a new UDI-Device Identifier (UDI-DI) or UDI-Production Identifier (UDI-PI).

Manufacturers should refer to guidance on our Unique Device Identification (UDI) hub about whether the planned change meets the threshold for a minor or major change and respond accordingly.

Maintaining and updating PCCPs

Manufacturers should periodically review the PCCP for ongoing relevance across the device lifecycle. A PCCP should be managed under document control within the manufacturer's quality management system with clear versioning and a record of differences between PCCP versions. Where a PCCP is revised, it may require re-assessment and acceptance by the comparable overseas regulator or us, depending on the nature of the changes.

Manufacturers should consider updating the PCCP and re-applying to us for the changes, where:

- proposed changes would extend beyond originally defined boundaries
- the underlying software architecture or model approach, or the training or validation dataset characteristics, change materially
- another ARTG Device Change Request or variation application is made for the device that affects PCCP assumptions; or
- new regulatory expectations (e.g. cyber security or equity requirements) alter the impact and risk assessment criteria.

Ongoing responsibilities

Post-market monitoring is a critical part of demonstrating that changes implemented under a PCCP remain safe and effective. For an overview, see: Understanding your post-market responsibilities for medical devices.

Sponsors must maintain sufficient records to determine whether a reported issue or adverse event is associated with a software change implemented under a PCCP. This includes traceability to the relevant pre-authorised change, associated verification and validation evidence, and risk management documentation. Sponsors should be able to provide this information to us on request, during post-market enquiries, audits, or compliance activity.

Evidence to demonstrate implementation of a PCCP

We may request information from the sponsor or manufacturer to confirm that a PCCP-covered change was implemented in accordance with the approved protocol. This may be in the context of a conformity assessment change or recertification application, a quality management system audit, a premarket application, or a post-market compliance activity.

We may request one or more of the following:

- A summary of the PCCP including a description of the changes, boundaries, and the change plan elements such as the verification and validation activities and acceptance criteria.
- Evidence that the PCCP was implemented including:
    - a manufacturer declaration that the change was implemented in accordance with the PCCP
    - an implementation summary or report cross-referencing the PCCP protocol, acceptance criteria, and results (including failures and how deployment was blocked or remediated), and
    - a mapping of the specific software versions, devices, ARTG entries, and UDIs (where relevant) impacted.

- Evidence that all products continue to meet the Essential Principles including real world evidence of the device's safety and performance.
- Evidence of performance evaluation against the predefined acceptance criteria including data description, inputs and outputs, metrics, statistical tests, and results.
- A traceability matrix mapping each planned (and each implemented) modification to the relevant modification protocol elements (methods, datasets, acceptance criteria) and to the impact assessment or risk controls (including cumulative assessment considerations).
- Quality management system document control and revision history for the PCCP, including change control records referencing PCCP sections, and training or competence records for personnel executing PCCP-based changes (including alignment to recognised standards where applicable, e.g. ISO 14971 and IEC 62304).
- Change history summary including baseline, incremental and cumulative performance summaries across implemented PCCP changes (where relevant to risk), including any failed acceptance criteria.
- How any failures were recorded and how deployment was blocked or remediated if criteria were not met. Include rollback and contingency arrangements (where relevant) if deployment resulted in unacceptable performance or safety risk.
- Impact assessment of benefits, risks, and mitigations, including cumulative impact.
- User transparency materials including release notes, labelling updates, training or communications, and the post-market monitoring approach.

Further support

Early engagement with us is encouraged prior to submitting an application that includes a PCCP. This may occur through established TGA regulatory engagement mechanisms, for example a pre-submission or regulatory engagement meeting, to allow us to address questions about the proposed PCCP's acceptability, including its scope, boundaries and the proposed verification and validation, and acceptance criteria.

Examples

1. Retraining to improve accuracy:

   A manufacturer wishes to use a PCCP to improve the accuracy of their software medical device, using real world evidence collected during the first 2 years of supply in Australia. Their device is intended for the measurement and visualisation of the eye and uses artificial intelligence to detect and diagnose eye conditions. The intended users are qualified health professionals (e.g. optometrists and ophthalmologists). They wish to improve the sensitivity and specificity of the software's detection and diagnosis of eye diseases or conditions through real-world monitoring. Included with the description of changes, change validation protocols and impact assessment, they submit their plans for real-world monitoring, specifying the data they will collect and how they will inform users of real-world monitoring. There will be no changes to the intended use population or intended purpose of the device.

2. Compatibility with a new type of imaging or scans:

   The device is AI-enabled software intended to interpret and analyse chest x-rays direct from the x-ray system, to highlight areas of concern that a radiologist should further investigate. The software will initially be compatible with 2 models of x-ray systems. However, the manufacturer plans to do further testing and release a new version in 3 years, which will be compatible with a further 2 models. There will be no change to the intended use population

and no change to the intended purpose. A PCCP could be used in this scenario to describe the processes needed to broaden the device compatibility, how the new model compatibility will be tested, validated, communicated, labelled and any user training provided.

3. Adding android compatibility to an iOS compatible application:

   The manufacturer intends to supply a mobile phone app initially with iOS compatibility, however, plans to supply an android compatible device within the next 3 years.

   There are 2 scenarios that could occur, depending on the device classification:

   1. If the device is classified as Class III:

      Under the Australian medical device regulations, Class III software medical devices with different operating systems are considered different kinds of medical device. This means a PCCP cannot be used to obtain pre-approval for the supply of the android app. A new device application would be required to supply an android compatible version of the app.

   2. If the device is classified as Class IIb or lower:

      A PCCP can be used to seek premarket approval via a Device Change Request application, as the 2 operating systems are considered the same kind of medical device.