

Predetermined Change Control Plan (PCCP)

PCCP is a framework that enables **predefined changes** to be **implemented without separate approval**

Purpose

Enable continuous learning and improvement of AI/ML models within a regulated environment

Includes

Change types, evaluation methods, implementation protocols, monitoring plans

Elements that should be included in PCCP

1. Description of Modifications

- Scope and types of permitted changes

2. Methodology

- Methods for implementing and validating changes

3. Impact Assessment

- Analysis of effects on safety and effectiveness

4. Monitoring Protocol

- Real-world performance tracking and reporting system

Permitted Changes

Performance improvements, data updates, algorithm optimization

Restricted Changes

Changes in intended use, addition of new indications

Reporting Requirements

Regular change logs and performance reports

 **Key Point:** PCCP strikes a balance between innovation and regulation, enabling continuous improvement of AI technology while maintaining patient safety