**IMDRF SaMD WG**
**Comment Form**

| Date: 12/8/25 | Document: [Essential Principles and Content of Predetermined Change Control Plans (N90)] |
|---|---|

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| GMTA | 47-49 | Introduction | The changes outlined in a PCCP may not always be specifically intended to ensure safety and effectiveness. For example, the PCCP may be submitted for a product improvement to support device use on additional operating systems or to expand functionality with other devices. Regardless of the cause for the PCCP, it should be implemented in a way that ensures safety and effectiveness. The proposed revision is intended to reflect this important nuance. | Recommend revising as follows:<br><br>"A Predetermined Change Control Plan (PCCP) allows manufacturers to seek authorization to implement planned changes while ensuring ~~to ensure~~ the continued safety and effectiveness of their medical device software." | |
| GMTA | 53 | Introduction | The use of the term "specific" to describe allowable changes in a PCCP is unclear and could be misleading. Rather than restricting PCCPs to narrowly defined changes, it would be more appropriate to assess proposed modifications based on whether the device continues to meet safety and effectiveness requirements. Imposing a requirement that only "specific" changes be included may unnecessarily limit the flexibility and usefulness of the PCCP framework. The suggested edit is intended to align with the Elements of a PCCP discussed in section 5.1. | Recommend revising as follows:<br><br>"1. the ~~specific~~ description of the planned changes to the medical device software," | |
| GMTA | 82-86 | Introduction | The draft N90 document acknowledges that PCCPs may be broadly applied to medical technologies, however the focus of this draft document is limited to medical devices software. US FDA has authorized several PCCPs to date, many of which are for medical technologies other than device software. Given the broad applicability of PCCPs to a diverse array of medical devices and technologies, we recommend either expanding the scope of this document beyond medical device software or issue a complementary draft document focused on PCCPs for medical devices (including IVDs), generally. | Recommend revising lines 82-83 as follows:<br><br>"PCCPs have the potential to be applied beyond medical device software to other areas of medical technology, and are already in use more broadly for medical devices in certain jurisdictions."<br><br>Proposed language that can be added to this draft document to expand its applicability beyond medical device software:<br><br>'While the framework, recommendations, and principles discussed in this document are presented in the context of medical device software, regulators may assess whether similar principles could be adapted for broader applications, including hardware modifications or medical technologies other than medical device software. This approach supports harmonization of PCCP implementation across medical device types." | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial





UNOFFICIAL

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| GMTA | 113-116 | Scope, 2.2 | It is our understanding that this document is intended to apply to all medical device software; including both software as a medical device (SaMD) and software in a medical device (SiMD). However, there is some ambiguity in the current phrasing. As written, it may be misinterpreted that the document is intended to apply only to a "subset of software" that meets the definition of a medical device in its own right (i.e., SaMD as defined in the referenced N10 document).<br><br>We recommend revising the phrasing in this section to more clearly affirm our understanding that, for the purposes of the N90 document, the distinctions between SaMD and SiMD are not relevant and that the recommendations in the document apply to all medical device software.<br><br>Please note that additional edits may be appropriate following resolution of GMTA's comments to lines 82-86 (i.e., our recommendation to expand the scope of the document to other medical technologies may necessitate additional changes to this section). | | |
| GMTA | 135-136 | References, 3 | The IMDRF N9 document is listed as a reference in section 3 but is not cited elsewhere in the N90 draft document. For clarity, please either remove this reference or explain its relevance within the N90 draft document. | Recommend revising as follows:<br><br>~~"3. IMDRF/RPS WG/N9 FINAL:2024 (Edition 4) Non-In Vitro Diagnostic Device 135 Regulatory Submission Table of Contents (nIVD ToC)"~~ | |
| GMTA | 142-144<br>&<br>174-176 | Essential Principles, 4<br>&<br>Fundamentals of a PCCP, 5 | The phrase "limited to modifications within the intended use" may be interpreted narrowly, potentially excluding labelling changes or usability improvements. This ambiguity could lead to inconsistent application across jurisdictions.<br><br>FDA has authorized PCCPs for changes to the device indications for use in limited circumstances (an illustrative example can be seen here). The suggested edits are intended to clarify that there may be instances where such changes are permissible. | Recommend revising lines 142-144 as follows:<br><br>"A PCCP describes the changes that a manufacturer intends to implement with enough specificity to ensure the continued, or improved, 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.~~"<br><br>Recommend revising lines 174-176 as follows:<br><br>"Changes included in a PCCP are limited to changes ~~within the~~ that do not modify the medical device software's original intended use or intended purpose.[1]"<br><br>Recommend revising footnote 1 as follows: | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| | | | Our suggested edits are intended to reduce ambiguity and add clarity to the discussion regarding changes to the intended use that align with some authorized PCCPs. | "Changes to the indications for use may be permissible in some instances, such as where the safety and effectiveness can continue to be assured. For example, model updates using newer data to expand the subset of a ~~an existing~~ patient population may be appropriate for inclusion in a PCCP, provided these changes fall within the original intended purpose. Other changes, such as to the device labeling, use conditions, or usability, may also be appropriate." | |
| GMTA | 169-172 | Fundamentals of a PCCP, 5 | The suggested edits are intended to clarify that the marketing authorization of a submission with a PCCP applies to both the current version of the device (which may be the subject of the marketing submission) as well as the future, modified, version of the device consistent with the changes described in the authorized PCCP. It is important to make clear that implementing modifications or changes in accordance with the authorized PCCP would not necessitate a new marketing submission. | Recommend revising as follows:<br><br>"A PCCP is an optional mechanism for manufacturers to convey, in their marketing submission to regulatory authorities, planned change(s) to their device that would otherwise require a new marketing submission. ~~in their submissions to regulatory authorities to support a marketing authorization of a device.~~ When authorized, the marketing submission and PCCP enable the manufacturer to market the device in its current state and with future modifications consistent with the PCCP. PCCPs may be utilized to support iterative and planned improvements to a device, while improving or ensuring continued safety and effectiveness." | |
| GMTA | 182 | 5.0 | "Device changes authorised 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".<br><br>It is recommended including alignment with international standards for medical device software (e.g., IEC 62304). As this is intended to help harmonise the implementation of PCCP to other regions it also makes sense to strengthen alignment through recognised international standards. | Suggested text:<br><br>Device changes authorised 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 and international standards for medical device software (e.g., IEC 62304). | |
| GMTA | 187 | 5.0 | "This is also important when a manufacturer wishes to make modifications to a previously authorised PCCP, so that a new authorised version can be adequately tracked" | Suggested text: | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| | | | While it is agreed that there could be modifications to previously authorised PCCPs, there is no mention of what level of modifications warrant an updated version as well as how these changes should be communicated to regulatory authorities in a way that would not add additional burden to manufacturers. The suggested wording is needed to ensure harmonisation for when a submission is needed for modifications made to an authorised PCCP. | This is also important when a manufacturer wishes to make modifications to a previously authorised PCCP, so that new authorised versions can be adequately tracked. Manufacturers may discuss with the regulatory authority that authorized the PCCP whether the modifications to the PCCP may be implemented without requiring a new PCCP or new marketing submission." | |
| GMTA | 194 | Fundamentals of a PCCP, 5 | Applying a one-size-fits-all approach across all changes may result in disproportionate regulatory burden for lower-risk changes, without a corresponding improvement in safety or performance. Tailoring PCCP expectations to the risk level of the device and the proposed changes, enables regulators and manufacturers to ensure that oversight is proportionate, efficient, and focused on patient safety. | Recommend adding the following to the paragraph ending on line 207:<br><br>PCCP documentation and review considerations may be adapted based on the risk level of the proposed changes to the medical device software. This approach ensures that the level of regulatory oversight and manufacturer effort is proportionate to the potential impact on patient safety and clinical outcomes. Regulatory authorities may also provide guidance on acceptable PCCP formats and expectations based on the nature and risk profile of proposed changes. | |
| GMTA | 209 | 5.1 | Please clarify the expectation using more precise terminology | Suggestion to change from:<br>"a justification for"<br><br>To:<br><br>"an explanation of" | |
| GMTA | 208-210<br>&<br>223-229 | Fundamentals of a PCCP, 5.1 & 5.1.1 | The justification should not be part of the Description of Changes as it a component of the Impact Assessment (see the text italicized in #3 below from lines 215-220). The suggested edit is intended to promote internal consistency within the document and eliminate the suggestion that redundant information should be included in the Description and Impact Assessment sections.<br><br>Lines 215-220: | Recommend revising 208-210 as follows:<br><br>"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."~~<br><br>Recommend revising 223-229 as follows: | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial



UNOFFICIAL

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| | | | "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 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 should include descriptive details ~~the list of individual~~ for each of the proposed device changes discussed in the PCCP and may include cross-references to the Impact Assessment section~~, as well as the specific~~ which discusses the 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." | |
| GMTA | 213-214 | Fundamentals of a PCCP, 5.1 | As noted in line 285, not all changes implemented within a PCCP require notification or communication to intended users. | Recommend revising as follows:<br><br>"…and, if applicable, how the changes will be communicated to intended users." | |
| GMTA | 256-258 | Fundamentals of a PCCP, 5.1.2 | We recommend clarifying that "end users" specifically refers to "intended users." Additionally, we propose revising the term "different" to "various" to more clearly reflect the need to consider various user groups within the intended use population. | Recommend revising as follows:<br><br>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 and~~ various intended users, as needed. | |
| GMTA | 259-262 | 5.1.2 | This sentence is currently unclear, please see suggested edits. It is however unclear if this is the intent of the sentence. | Performance evaluation of the medical device software is important to ensure that the ~~current~~ medical device software performance meets ~~and~~ the pre-specified acceptance criteria for all proposed changes ~~will continue to be met~~. | |
| GMTA | GMTA | Fundamentals of a PCCP, 5.1.2 | It is not possible for the PCCP's Change Plan to have details about the *implemented* changes as the changes are *planned,* not implemented, at the time of regulatory review. | Recommend revising as follows:<br><br>"Specifically, the Change Plan may provide, as applicable, details on the planned ~~implemented~~ changes, including:" | |
| GMTA | GMTA | Fundamentals of a PCCP, 5.1.2 | This bullet point is open-ended and does not provide sufficient context to support harmonization or meaningfully add clarity to the expected content for a PCCP. Collectively, the items in lines 270-275 provide sufficient clarity for what content to include in the Change Plan. Therefore, we recommend deleting this bullet from the list. | Recommend revising as follows:<br><br>"~~related evidence to support authorization of a PCCP.~~" | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| GMTA | GMTA | 5.1.2 | It is critical that the criteria are shown to be met. Please see suggested 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 do ~~can~~not meet predefined acceptance criteria per the methods specified in the Change Plan. | |
| GMTA | 288-291 | 5.1.2 | The current wording is unclear. It is not appropriate to require that all information from the previous sentence be provided to users in situations where the software does not function as intended after implementation. In such cases, the manufacturer would follow their quality management system to assess and address the issue, including assessing what, if any, communication needed to be provided to intended users. The rest of this section accurately describes what should be included in the update procedures, so this sentence could be removed. | Please revise as follows:<br><br>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.~~ | |
| GMTA | 297-298 | Fundamentals of a PCCP, 5,1,2 | A phrase “minor software release modification” is subjective. Furthermore, a “minor” change would likely not warrant authorization in a PCCP because it would not otherwise require a new marketing authorization (per line 181). | Recommend revising as follows:<br><br>“… (e.g., ~~minor software release~~ software release notification that has minimal operational impact vs. advanced warning for ~~major~~ changes that may have significant operational impact). “ | |
| GMTA | 320-322 | Fundamentals of a PCCP, 5.1.3 | The current wording implies that when preparing the Impact Assessment, each proposed change should be compared to the original, unmodified device software. In practice, a given change/modification in the PCCP may be dependent on prior change(s) within the same PCCP (e.g., PCCP Change #2 builds on PCCP Change #1). Therefore, comparing each change to the unmodified version may not be meaningful. Additional clarification would be helpful to address scenarios where changes within the authorized PCCP are interdependent or are planned to be implemented sequentially.<br><br>We recommend clarifying that the comparison for each proposed change should be made to the most appropriate version of the medical device software, in accordance with the respective jurisdiction’s review policies. | | |
| GMTA | 324-328 | 5.1.3 | These examples, particularly the one about unintended bias in AI devices, may be overly specific for explaining the concept of risks. For clarity and to prevent confusion, it is recommended removing these examples. | Please revise as follows: | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| | | | | Discussion of the anticipated benefits and risk~~s, 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; | |
| GMTA | 342-346 | Benefits and Challenges of PCCPs, 6.1 | The proposed edits are intended to enhance clarity and affirm the that changes can be implemented without requiring a new marketing submission, consistent with the purpose of the PCCP. | Recommend revising as follows:<br><br>"When appropriately utilized, PCCPs allow for authorized~~, well documented~~ modifications to ~~occur~~ be implemented after the medical device software has been placed on the market, without a new marketing submission. PCCPs~~,~~ enabl~~eing~~ patients and healthcare systems to benefit from accelerated access to innovation while regulators and manufacturers maintain regulatory compliance and device safety." | |
| GMTA | 354-362<br><br>& 366-368 | Benefits and Challenges of PCCPs, 6.1.1 | This section risks overstating the purpose of PCCPs. While some PCCPs may be intended to incorporate new clinical evidence or address findings from real-world use, others may simply implement planned functionality enhancements, such as supporting device use on additional operating systems. Overemphasizing the benefits or purpose of PCCPs could unintentionally lead some jurisdictions to allow PCCPs only for changes that respond to new evidence or real-world use, rather than for other types of enhancements.<br><br>We propose revisions to focus on the ability of PCCPs to facilitate more timely access to software improvements, which can encompass both updates that address safety and planned product enhancements. | Recommend revising lines 354-362 as follows:<br><br>"PCCPs may be leveraged to 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.~~<br><br>By supporting a proactive and flexible update process, PCCPs help to ensure ~~can enable manufacturers to respond swiftly to real-world use, ensuring~~ patients have timely access to technological advancements."<br><br>Recommend revising lines 366-368 as follows:<br><br>"For patients, this means timely access to important medical device software improvements ~~potential safety and compliance issues can be identified and~~ | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial



UNOFFICIAL

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| | | | | ~~addressed more swiftly, keeping patient safety at the forefront and ensuring more reliable and up-to-date medical device software~~." | |
| GMTA | 373-375 | Benefits and Challenges of PCCPs, 6.1.2 | The meaning of this sentence, particularly the references to "improving response time" and "risk mitigation," is unclear.<br><br>Further, the PCCP framework does not require manufacturers to specify or adhere to a timeline for implementation of the changes. | Recommend deleting the following:<br><br>"Additionally, PCCPs could provide a streamlined mechanism for deploying updates ~~in a predetermined timeframe thereby improving response time and risk mitigation~~." | |
| GMTA | 385-387 | Benefits and Challenges of PCCPs, 6.1.2 | The current language suggesting that PCCPs enable more precise and adaptive care may overstate their intended role, as not all PCCPs are designed to facilitate adaptive care. To avoid misrepresenting their purpose, we propose edits that generalize the benefits of PCCPs for patients. This will ensure the N90 document accurately reflects that PCCPs can support a range of improvements, ultimately benefiting patients and users, without implying that all PCCPs are focused on adaptive care. | Recommend revising as follows:<br><br>"Over the lifetime of the product, the administrative efficiency that results from using PCCPs can lead to continuous improvements that provide patients and users with more timely access to important device updates ~~enable patients or users to receive more precise and adaptive care, improving treatment accuracy and effectiveness~~." | |
| GMTA | 422-474 | Benefits and Challenges of PCCPs, 6.2.1, 6.2.2, 6.2.3, 6.2.4 | The content in sections 6.2.1, 6.2.2, 6.2.3, and 6.2.4 are subparts under section 6.2 which is focused on "Challenges of PCCPs." We appreciate the potential challenges that PCCPs may present. However, in the spirit of promoting harmonization and ensuring PCCPs achieve their intended benefits, we recommend the discussions regarding these challenges be framed in the context of potential solutions and best practices for regulators and manufacturers. | Create a new section titled "Addressing Challenges and Adopting PCCP Best Practices" and move the content in the subparts of 6.2 to this new section. | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| GMTA | 423-430 | Benefits and Challenges of PCCPs, 6.2.1 | The phrase “evidence gathering” is unclear, as “evidence” is not a required element for a PCCP. Rather, manufacturers submitting a PCCP must develop *plans* for obtaining the necessary evidence. To more accurately reflect the PCCP process, we propose replacing “evidence gathering” with “planning,” since planning is the essential step in developing a PCCP.<br><br>PCCPs require significant effort from organizations of all sizes, not just smaller companies. | Recommend revising as follows:<br><br>“Submissions with PCCPs ~~will~~ may require additional preparation time, compared to a submission without a PCCP, due to the need for extensive ~~evidence gathering and~~ planning, time to prepare the PCCP documentation, and conduct associated activities (e.g., risk analysis) ~~creation compared to a traditional submission~~. This can increase submission preparation time for manufacturers and raise initial costs, ~~and extend the duration between preparation of a submission and a submission reaching the appropriate regulatory authority~~, potentially<br><br>increasing the time-to-market and return on investment. This may present a challenge for ~~smaller~~ manufacturers, given the initial resource investment and expertise required to prepare the PCCP documentation ~~and the necessity for sourcing expertise and experience to gather sufficient evidence~~.” | |
| GMTA | 437-438 | Benefits and Challenges of PCCPs, 6.2.2 | We recommend the N90 document include additional information, regarding review timelines to promote harmonization among regulators and consistent understanding among all stakeholders.<br><br>Consistently excessive or extended review timelines for submissions with PCCPs could hinder the intended benefits of a PCCP program. | Recommend revising as follows:<br><br>“~~Other~~ While jurisdictions could have different review timelines and authorization processes due to the inclusion of a PCCP, significantly disparate timeframes within a given jurisdiction for submissions with and without PCCPs may diminish the value of the intended regulatory efficiency generated by PCCPs; resulting in low utilization of PCCPs among device manufacturers and extended timelines for patient access to device improvements.” | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

| Name/ Organization | Line Number | Section | Comments | Proposed change | Resolution |
|---|---|---|---|---|---|
| GMTA | 439-444 | Benefits and Challenges of PCCPs, 6.2.2 | The draft document notes that the inclusion of a PCCP can result in a more complex review process, however it does not discuss potential solutions to help mitigate the challenges. Based on our experiences with PCCPs, we have found review practices that promote dialogue between regulators and manufacturers, such as interactive review (e.g., regulator-initiated conversations during the review) and pre-submission interactions (e.g., meetings and demonstrations prior to submitting the marketing submission with PCCP) can facilitate regulators' understanding of the device and the proposed PCCP thereby enhancing review efficiency. Including these proven solutions in this document can help regulators and manufacturers have a mutual understanding of options and techniques that can mitigate the identified challenges.<br><br>The recommendation to focus on a "limited number of proposed changes" places undue emphasis on the number of changes included in a PCCP. In practice, factors such as the impact, risk, and complexity of the proposed changes are likely to be more relevant to a regulator's assessment of whether a PCCP can be authorized. Therefore, we recommend removing the reference to limiting the number of changes in a PCCP. | Recommend revising as follows:<br><br>"In general, from a regulator's perspective, the inclusion of a PCCP and its proposed modifications can introduce a more complex assessment process. Utilization of practices that promote dialogue between regulator and manufacturer during the assessment process can help to facilitate more timely review of regulatory submissions. ~~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." | |
| GMTA | 471-472 | | This sentence implies that the reliance considerations for PCCP differ from general reliance principles. Reliance concepts established by the World Health Organization (WHO) and IMDRF apply broadly. If a regulator wishes to rely on another authority's PCCP decision or underlying evidence, they can already do so within the framework of general reliance models. There is no need to establish separate or additional reliance mechanisms specifically for PCCPs. | Recommend revising as follows:<br><br>~~"Harmonization in reliance will need to be established."~~ | |
| End of Table | | | | | |

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial



UNOFFICIAL