SCCL Policy

Clinical and Product Assurance (CaPA) Framework for Category Tower Service Providers (CTSPs)

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Questions on this policy should be addressed to	capa@supplychain.nhs.uk

Version	Date	Amended By	Approved By	Details
1.0	22.07.2019	Charlie Knell	Jo Gander	Initial Document
2.0	08.08.2019	Charlie Knell	Jo Gander	References to mini-competitions removed, NCP definition updated, Non-Catalogue Range Extensions included
3.0	31.01.2020	Charlie Knell	Jo Gander	Minor adjustments throughout post 6-month test phase, listed via webinar here: <embed webinar link>

Contents

1. Scope

1.1 This policy sets out the Clinical and Product Assurance (CaPA) Framework, to support Category Tower Service Providers (CTSPs) in meeting CaPA requirements.

2. Introduction

2.1 Supply Chain Coordination Limited (SCCL) at NHS Supply Chain is committed to supplying products that are value for money, clinically assured as safe, fit for purpose, and where possible innovative. To fulfil these criteria, product category frameworks must be demonstrably representative of the needs of health and care professionals, other staff, patients, carers, and other users.

3. Clinical and Product Assurance (CaPA) Framework

3.1 The SCCL CaPA team provide clinical assurance at each of the following stages of the CTSP product procurement process, through systematic and consistent application of agreed assurance criteria, as illustrated by Figure 1. below:

- Category Strategy – for Category Council
- Sourcing Strategy – for Category Council
- Product Evaluation Report – for Commercial Award Review Forum (CARF).

3.2 In addition, the CaPA team provide clinical assurance when:

- A Sourcing Strategy is extended
- Alternative products are added to a framework mid-contract (on delist)
- New products are added to a framework mid-contract (range extension).

3.3 A series of PowerPoint Templates (Category Strategy, Sourcing Strategy, Product Evaluation Report, and supplementary Nationally Contracted Product (NCP) Evaluation Report), have been developed with CTSPs to capture the information required by CaPA.

3.4 All Templates include integral guidance notes which must be followed, and completed sample Templates are available to further support CTSPs.

3.5 CTSPs must not remove slides from PowerPoint Templates, adjust the order of the slides therein, or edit slides. All slides require completion to support CaPA assurance.

3.6 Each CTSP is supported by an allocated CaPA Product Assurance Specialist (PAS) or a Product Assurance Support Officer (PASO), whose input should be sought at **First Draft Template** completion to allow ample time for liaison to ensure all requirements are met, submitted along with prior supporting documents, for example:

Template submitted to CaPA:	Please also submit:
Sourcing Strategy	Approved Category Strategy
Product Evaluation Report	Approved Sourcing Strategy

3.7 CTSPs should also submit **Draft NCP Product Evaluation Report Templates** to capa@supplychain.nhs.uk, copying in their PAS/PASO, for iterative progress review and feedback at least 10 working days before the Invitation to Tender (ITT) date - completed, except for awarded and alternative suppliers. At this **NCP ITT Gateway**, the review will focus closely on specification, stakeholder involvement, and evaluation methodology.

3.8 CTSPs should submit all **Final Version Templates** (including all completed cross-functional Category Strategy and Sourcing Strategy slides) via capa@supplychain.nhs.uk and their associated Category Tower Manager (CTM), at least 10 working days before Category Council and CARF (Product Evaluation Report Templates should be accompanied by the completed draft CaPA CARF slide for review). This submission deadline supports final CaPA Assurance review only, and no further iteration - a response of "Met" or "Not Met" will be provided. Late submissions without prior agreement will be rejected.

3.9 The CaPA Lead Assurance PAS/PASO will monitor the CaPA mailbox, and will automatically return any Templates submitted with missing, edited, or incomplete slides, for re-submission. CaPA record actual CTSP submission dates against required submission dates, presenting monthly reports. Submission is recorded using the date of receipt of fully completed Templates.

3.10 It is essential that CTSPs meet required Template submission deadlines to ensure time is available for CaPA review, Head of CaPA review, and completion of CaPA Assurance Tools.

3.11 **Please complete all parts of each Template in line with this Policy and the in-Template guidance notes before submission, as failure to do so may delay final approval.**

3.12 To support a consistent and repeatable assurance process and assist CTSPs with Template completion, a 'CaPA Assurance Framework Template Completion Checklist for CTSPs' (Appendix 1) has been developed, for CTSPs to use prior to submission of Templates to CaPA.

3.13 **Please email all Final Version Templates for review to capa@supplychain.nhs.uk, copying in the allocated PAS/PASO, to enable data monitoring, and cover during absence at meetings, events, and on leave. To support business continuity, documents may be assured by any PAS/PASO other than that allocated to the CTSP.**

3.14 To support reporting oversight, consistency, and business continuity in the absence of the allocated PAS/PASO, an 'Ongoing CaPA Feedback Record for CTSPs' has been developed for the PAS/PASO to complete and share with the CTSP and CTM at each Template review.

3.15 CTSPs should note that ongoing PAS/PASO feedback does not constitute final approval until Final Version Template review has taken place, as CaPA approval rests upon close examination of the entire completed Template and supporting evidence – although stages formally agreed via the 'Ongoing CaPA Feedback Record for CTSPs' shall stand.

3.16 **It is the CTSP's responsibility to ensure completion of all parts of each Template in line with this Policy and the in-Template guidance notes before submission to CaPA.**

Clinical and Product Assurance (CaPA) Framework

CaPA Aim: All Products Sourced are Safe, Fit for Purpose, and Innovative

Category Strategy	Sourcing Strategy	Product Evaluation Report
CaPA approval required for Category Council CTSP submits to CaPA at First Draft, and >10 working days (Final Version Review) before Category Council	CaPA approval required for Category Council CTSP submits to CaPA at First Draft, and >10 working days (Final Version Review) before Category Council	CaPA approval required for Commercial Award Review Forum (CARF) CTSP submits to CaPA at First Draft, >10 working days before Invitation to Tender date for NCPs (without awarded/alternative suppliers), and >10 working days (Final Version Review) before CARF
Initial:	**Updated:**	**Final:**
Stakeholder involvement	Stakeholder involvement	Stakeholder involvement
Risks identified and mitigated	Risks identified and mitigated	Risks identified and mitigated
Quality and safety concerns addressed	Quality and safety concerns addressed	Quality and safety concerns addressed
National data intelligence gathered	National data intelligence gathered	National data intelligence gathered
Purpose by Lot and evaluation level	Purpose by Lot and evaluation level	Purpose by Lot and evaluation level
Stakeholder product criteria	Stakeholder product criteria	Stakeholder product criteria
Range rationalisation plan	Range rationalisation plan	Range rationalisation plan
Range optimisation plan	Range optimisation plan	Range optimisation plan
Nationally contracted products	Nationally contracted products	Nationally contracted products
	Technical evaluation	Technical evaluation
		Product criteria, specification, and suppliers
		Product hierarchy

Figure 1. CaPA Framework

4. Requirements

4.1 Stakeholder involvement

4.1.1 Purpose

NHS Supply Chain products must meet the needs of users, including patients, carers, and others (such as breast-feeding mothers and their babies), health and care professionals, and other staff. User-centric evaluation and development ensures that ranges are rationalised and optimised to meet agreed user product criteria and quality requirements, as illustrated by Figure 2. below:

Figure 2. User-Centric Range Management, Optimisation, and Evaluation

4.1.2 Expectations

4.1.2.1 Involve stakeholders early, from Category Strategy through to Sourcing Strategy and Product Evaluation Report development, to ensure that each framework is created to meet their needs; to check impartiality, local declaration of interest forms should be used.

4.1.2.2 Involvement should consist of open-ended questions, to enable stakeholders to drive required change, rather than simply asking stakeholders to approve a current range or specification; user needs, human factors, opportunities for innovation, and clinical requirements should be explored, for improved physical quality standards.

4.1.2.3 Ensure broad national geographical representation of stakeholders, and include National Expert Reference Groups, National Strategy Groups, Royal Colleges, Getting it Right First Time (GIRFT) leads, Clinical Reference Groups, Patient, Carer, and Other

User Groups, NHS Acute Trusts, Ambulance Trusts, Mental Health Trusts, Community Trusts, Clinical Commissioning Groups (CCGs) and their GP Practice Forums, Primary Care Networks, Sustainability and Transformation Partnerships (STPs)/Health and Care Partnerships (HCPs) and their Local Authorities, Reference Trusts, any Trusted Customer, etc, as applicable.

4.1.2.4 Involving patients, carers, and other users is important in improving all aspects of care, including patient safety, patient experience, and health outcomes – giving people the power to live healthier lives; consider involvement via liaison with National Expert Reference Groups, National Strategy Groups, National Expert Patient Groups, Service User Networks, Medical Schools, Royal Colleges, National Institute for Health Research (NIHR) Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), Academic Health Science Networks (AHSNs), NHS Patient and Public Involvement and Social Care Co-Production forums, etc.

4.1.2.5 As medicine advances, health needs change, and society develops, integrated care services fit for the future as per the NHS Long Term Plan[1] (drawn up by frontline staff, patient groups, and national experts), support healthcare that is more personalised and patient-centred, focused on prevention, and delivered in the community, out of hospital. Therefore when developing stakeholder groups, consider the range of available markets, including those delivering NHS-funded care, for example in patients' homes, schools, dental practices, care homes, nursing and residential homes, GP practices (including Primary Care Network Buying Groups), and the voluntary, community, and independent sectors delivering NHS-funded care, as illustrated by Figure 3. below:

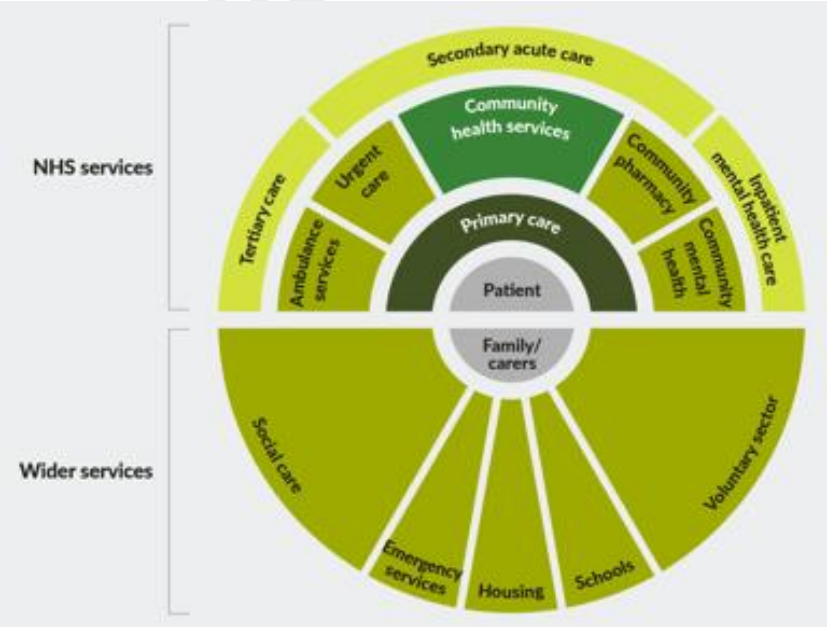


Figure 3. Health and Care Service Landscape [2]

[1] NHS Long Term Plan, NHS England, 2019
[2] Community Services Explained, The King's Fund, 2019

4.2 Risks identified and mitigated

4.2.1 Purpose

Risks to implementing each strategy require identification and management, to proactively minimise the impact of issues arising and maximise benefits, as illustrated by Figure 4. below. Liabilities exist where risks are not managed.

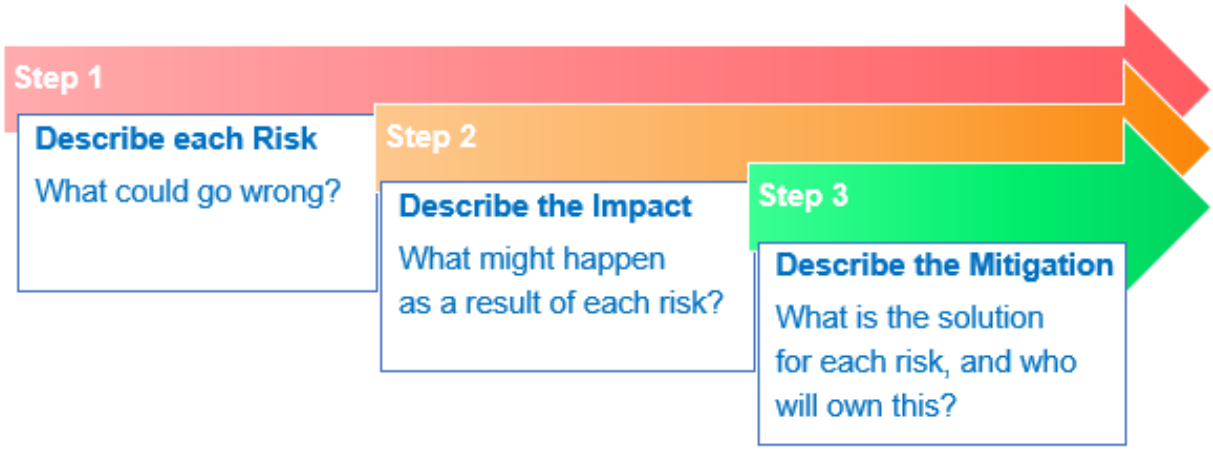


Figure 4. Risk Management

4.2.2 Expectations

4.2.2.1 Describe each risk, considering sustainability risks, financial risks, environmental risks, political risks, strategic risks, clinical risks, evaluation risks, product assurance risks, suppliers and products of concern, commodities, sole source, etc.

4.2.2.2 Describe the potential impact/effect of the risk to implementing each strategy and any associated evaluation.

4.2.2.3 Explain how each risk will be mitigated/treated, and for each risk add the job title of the action owner.

4.3 Quality and safety concerns addressed

4.3.1 Purpose

Products presenting a risk as a result of quality or safety concerns must be removed from the supply chain to prevent harm, adverse events, and user dissatisfaction, unless corrective actions have been taken. Corrective actions comprise solutions to control a problem, i.e. to prevent repeated harm, adverse events, and user dissatisfaction, by elimination (designing the problem out), as illustrated by Figure 5. below. Administrative controls such as training,

scheduling, and user instruction are far less effective as they rely on processes, experience, and memory. Liability exists where corrective action is not taken.

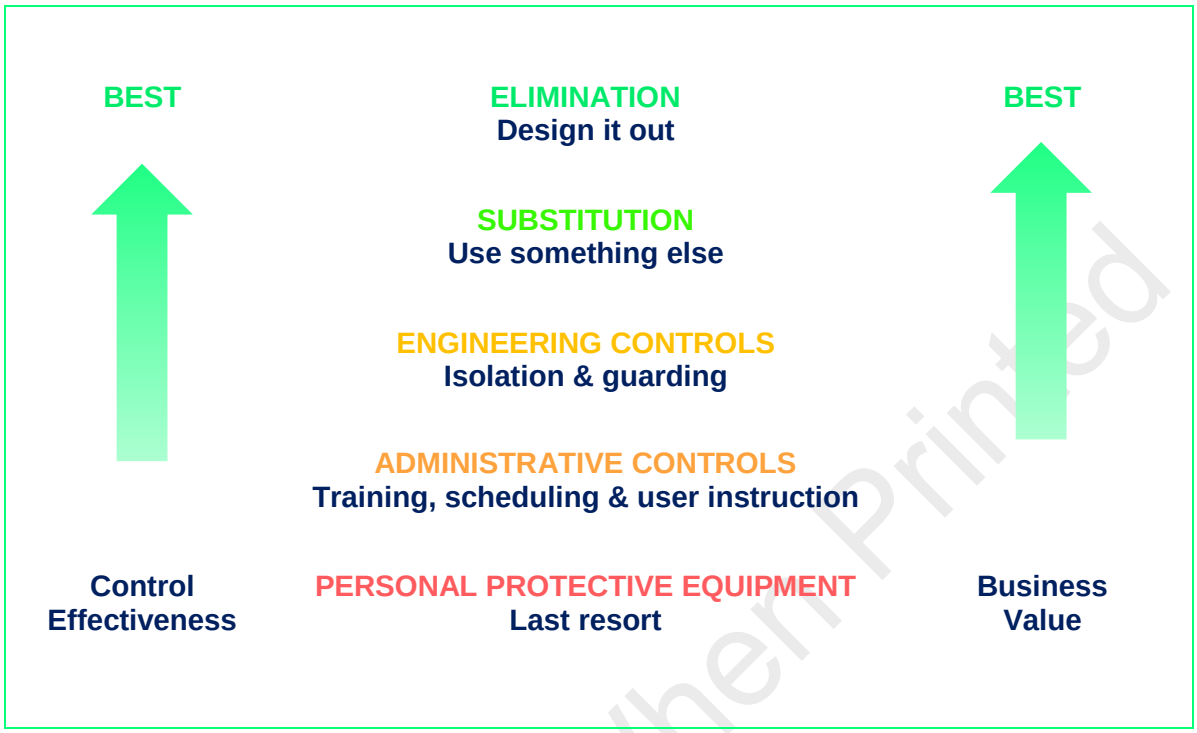


Figure 5. Hierarchy of Safety Controls

4.3.2 Expectations

4.3.2.1 Quality and safety concerns raised in and since the last strategy period must be described, including Medicines and Healthcare Products Regulatory Agency (MHRA) Alerts, Product Recalls, Field Safety Notices (FSNs), Important Customer Notices (ICNs), Quality Issues, Complaints, Exceptions, etc. – along with a summary of corrective actions taken to address any concerns raised and prevent a recurrence.

4.3.2.2 International Organisation for Standardisation (ISO) standards ISO 9001: Quality Management System and ISO 13485: Medical Devices use feedback from sources such as complaints, post-market surveillance, handling of non-conformities, corrective actions and preventive actions. Where quality and safety concerns have been raised, review of the manufacturer/supplier ISO Quality Monitoring Report or similar (i.e. ISO 9001 and ISO 13485, as applicable) including sampling (each batch), etc. covering the previous 12 months, should be described – along with a summary of corrective actions taken to address any concerns raised and prevent a recurrence.

4.3.2.3 The subsequent impact of quality and safety concerns raised on the new framework product criteria, evaluation, and specification should be summarised.

4.4 National data intelligence gathered

4.4.1 Purpose

To optimise the benefits of each framework across the health and care landscape, it is essential to ensure evidence-based development in line with national strategic drivers, expert opinion, and best practice guidance, as illustrated by Figure 6. below:

Figure 6. National Data Intelligence for Evidence-Based User Support

4.4.2 Expectations

4.4.2.1 Early expert stakeholder involvement and liaison will help to identify relevant sources of data intelligence – and findings from national data intelligence gathered that have an impact upon the new framework should be briefly summarised, including findings from any National Strategy Groups, National Expert Reference Groups, Best Practice or Royal College Guidelines, National Institute for Health and Care Excellence (NICE) Guidance, NHS England, NHS Improvement, Getting it Right First Time (GIRFT), Healthcare Safety Investigation Branch (HSIB), literature search, current research, etc.

4.4.2.2 Where findings have been identified that will have an impact upon the new framework, enter the associated Lot number and briefly summarise how each finding will affect the new framework product criteria, evaluation, and specification, including any new or emerging market areas or users.

4.5 Purpose by Lot and evaluation level

4.5.1 Purpose

Understanding the rationale for each Lot (including clinical purpose, where applicable), is important in determining appropriate ranges, indication for use, and user groups, to support effective stakeholder involvement in evaluation. Work with stakeholders is essential, to understand their expectations from each product range, explore unmet needs, and test and compare samples across ranges to identify expected qualities and performance thresholds. Minimum evaluation levels (Limited, Wide, or Specific), are determined by Medical Device Regulation (MDR) Class, and In-Vitro Diagnostic Regulation (IVDR) Class, as illustrated by Figure 7. below (NB MDR/IVDR Class does not preclude further involvement as required):

Low Risk	Medium Risk	High Risk
Non-Medical and MDR Class I	**MDR Class IIa and MDR Class IIb**	**MDR Class III**
IVDR Class A and B	**IVDR Class C**	**IVDR Class D**
• **Limited** stakeholder involvement, including health and care professionals and other staff, and patients, carers and users (where products are directly used by them), i.e. email surveys • Independent laboratory testing a possibility for all IVDR Classes • Technical evaluation to ensure all products are compliant with required regulatory and safety standards.	• **Wide** stakeholder involvement, including health and care professionals and other staff, and patients, carers and users (where products are directly used by them), i.e. email surveys, face-to-face or telephone interviews/surveys, workshops, clinical simulations, table-top reviews • Independent laboratory testing a possibility for all IVDR Classes • Technical evaluation to ensure all products are compliant with required regulatory and safety standards.	• **Specific** expert and specialist stakeholder involvement, including where appropriate health and care professionals and other staff, and patients, carers and users (where products are directly used by them), i.e. email surveys, face-to-face or telephone interviews/ surveys, workshops, clinical simulations, table-top reviews, independent laboratory testing • Independent laboratory testing a possibility for all IVDR Classes • Technical evaluation to ensure all products are compliant with required regulatory and safety standards.

Figure 7. Required Product Evaluation Levels by MDR and IVDR Risk Class

4.5.2 Expectations

4.5.2.1 All ranges and products require stakeholder involvement in evaluation - this may be limited to a simple email survey by Lot, for example where products are Low Risk, which may determine areas for more in-depth, higher level evaluation; where possible (if not explain why), samples should be provided for stakeholders to test within their clinical/live settings.

4.5.2.2 As a minimum, an email survey to all known stakeholders is required at Category Strategy and Sourcing Strategy stages, to decide where best to focus product evaluation.

4.5.2.3 The CTSP is responsible for ensuring that all products undergo technical evaluation (see section 4.9) to ensure compliance with required regulatory and safety standards.

4.6 Stakeholder product criteria

4.6.1 Purpose

NHS Supply Chain customers - health and care professionals, other staff, patients, carers, and other users - in tandem with representatives of National Strategy and Expert Reference Groups - are uniquely able to advise regarding the required features and benefits of products across a range, specific product criteria, and the most appropriate evaluation processes, and to recommend supplier innovation where necessary. Figure 8. below outlines the factors to consider when determining which products to evaluate with stakeholders, to represent whole ranges:

STEP 1: Consider the full range of products in scope:

- Total number of products
- Product sub-lots
- Total number of products in each sub-lot

STEP 2: Reduce the number of products requiring evaluation:

- Different product sizes – Usually, evaluation of only one size is necessary
- Different product colours – Usually, evaluation of only one colour is necessary
- Different units of issue – Usually, evaluation of only one unit of issue is necessary
- Products unsold over the past 12 months or longer – Consider removal from catalogue
- Obvious unwarranted product duplication or variation – Consider removal from catalogue
- Previous recent/ongoing evaluation – Consider if precludes further evaluation at this stage

STEP 3: Consider quality issues that may lead to the removal of products, e.g.:

- Complaints, exceptions, customer notices – Products involved may not be fit for purpose
- MHRA Alerts – https://www.gov.uk/drug-device-alerts
- NHSI Alerts – https://improvement.nhs.uk/news-alerts/?articletype=patient-safety-alert
- National Strategy and Expert Reference Group – Recommendations

STEP 4: Consider the most appropriate type of evaluation by MDR and IVDR Class, e.g.:

- Non-Medical, MDR Class I, IVDR Class A and B – Limited stakeholder involvement
- MDR Class IIa and Class IIb, IVDR Class C – Wide stakeholder involvement
- MDR Class III, IVDR Class D – Specific expert and specialist stakeholder involvement

(please see Figure 7.)

STEP 5: Consider stakeholder requirements, e.g.:

- Patient, carer, and other user needs, including innovation and human factors
- Health and care professional and other staff needs, including innovation and human factors
- National strategy and expert reference group needs and latest best practice
- Markets – acute, community, mental health, primary, and social care, etc.

Figure 8. Selection of Products for Evaluation with Stakeholders

4.6.2 Expectations

4.6.2.1 Involvement should consist of open-ended questions, to enable stakeholders to drive required change, rather than simply asking stakeholders to approve a current range or specification; user needs, human factors, opportunities for innovation, and clinical requirements should be explored, for improved physical quality standards, isolating critical criteria for evaluation (including where possible and reasonable, technical measures), and as a minimum, reflecting user preferences and exclusions.

4.6.2.2 For each Lot, enter the stakeholders and involvement method(s) used for each sub-lot, and the date on which involvement took place, or will take place.

4.6.2.3 Describe any new product criteria identified by stakeholders for the final specification, as a result of the involvement exercise.

4.7 Range rationalisation plan

4.7.1 Purpose

NHS Supply Chain must ensure that products offered across a range meet evolving requirements, without unwarranted variation of products as per the Carter Reports[3][4][5], or unnecessary duplication, in order to keep the catalogue safe, effective, useful and relevant, as illustrated by Figure 9. below:

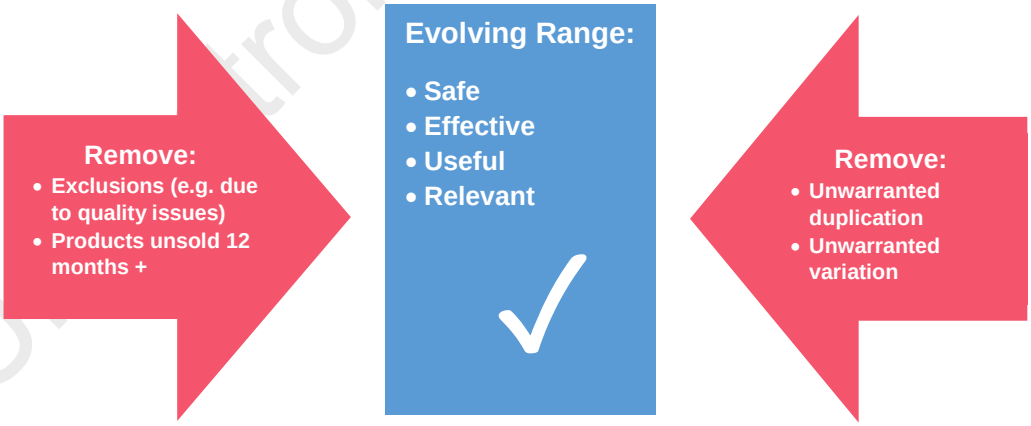


Figure 9. Range Rationalisation

[3] Operational Productivity and Performance in English NHS Acute Hospitals: Unwarranted Variations, Department of Health, 2016
[4] NHS Operational Productivity: Unwarranted Variations, Mental Health Services, Community Health Services, 2018
[5] Operational Productivity and Performance in English NHS Ambulance Trusts: Unwarranted Variations, 2018

4.7.2 Expectations

4.7.2.1 Plans to refine the range should be summarised, e.g. NCPs planned, exclusions to be removed due to quality issues, products unsold over the past 12 months or longer to be removed, unwarranted duplication of products to be removed, unwarranted variation of products to be removed, along with the date by which each action will be completed; NB All NCPs should be accompanied by the supplementary NCP Product Evaluation Report for/at CARF.

4.7.2.2 Framework size should be reviewed to ensure that it is not too large to reflect ranges effectively within the catalogue, and support users.

4.7.2.3 If no range rationalisation is planned, this must be stated, along with an explanation.

4.8 Range optimisation plan

4.8.1 Purpose

NHS Supply Chain must be responsive in ensuring that as medicine advances, health needs change, and society develops, products offered across a range meet evolving stakeholder requirements, as illustrated by Figure 10. below:

Figure 10. Range Optimisation

4.8.2 Expectations

4.8.2.1 Plans to improve the range should be summarised, i.e. on liaison with stakeholders to identify user requirements, liaison with suppliers to implement stakeholder requirements, including product criteria, evaluation, and specification changes as a result of stakeholder involvement and information gathered, innovation, consideration of human factors, and any new or emerging market areas or users.

4.8.2.2 If no range optimisation is planned, this must be stated, along with an explanation.

4.9 Technical evaluation

4.9.1 Purpose

Aside from reflecting the criteria identified by and agreed with stakeholders, as distributors it is essential that CTSPs check that all products procured for distribution via NHS Supply Chain meet the required technical, safety, and regulatory standards, as illustrated by the Medicines and Healthcare Products Regulatory Agency (MHRA) requirements[6] in Figure 11. below. CaPA has a duty to seek assurance that these requirements are met, however it is also the duty of the CTSP as a distributor (via their technical team or similar) to ensure that all products procured undergo a technical evaluation for compliance with required regulatory and safety standards.

Figure 11. MHRA Requirements to be Met

4.9.2 Expectations

4.9.2.1 All product specifications reflect the criteria identified by and agreed with stakeholders.

4.9.2.2 Manufacturers/suppliers are able to meet new MDR and IVDR requirements, i.e. post-market vigilance (reactive) and surveillance (preventative).

[6] An Introductory Guide to the Medical Device Regulation (MDR) and the In-Vitro Diagnostic Medical Device Regulation (IVDR), Medicines and Healthcare Products Regulatory Agency, 2019

4.9.2.3 Manufacturers/suppliers can provide supply continuity with contingency arrangements in place to prevent and manage supply interruption.

4.9.2.4 MDR and IVDR classifications are confirmed for each product to be procured.

4.9.2.5 Indications for use are confirmed for each product to be procured.

4.9.2.6 Contraindications for use are confirmed for each product to be procured.

4.9.2.7 Clinical, inventory, and transport storage requirements are confirmed where required, and maintained for each product to be procured.

4.9.2.8 Cleaning, decontamination, servicing, and maintenance requirements are confirmed where required for each product to be procured.

4.9.2.9 All Declarations of Conformity are confirmed as valid where required for each product to be procured.

4.9.2.10 All required Registration Certificates are confirmed as valid for each product to be procured - CTSPs should investigate and ensure compliance with applicable requirements.

4.9.2.11 Notified Body number on the device where required for each product to be procured.

4.9.2.12 Unique Device Identifier (UDI) on device label as required.

4.9.2.13 CE mark on packaging and if possible, on the device where required for each product to be procured.

4.9.2.14 Safety/Technical Standards identified and met for each product to be procured. CTSPs must access and review required product technical, safety, and regulatory standards, including ISO and BSI standards, when scoping activity with Suppliers for a Framework, to ensure product safety and regulatory compliance.

4.9.2.15 ISO 9001 and ISO 13485 certification demonstrates products to be procured are in scope of the ISO audit, and manufacturer/supplier ISO 9001 and ISO 13485 (as applicable) Quality Monitoring Reports (covering 12 months) demonstrate that corrective actions have been taken as required, e.g. on routine sampling (each batch), complaints, etc. - where corrective actions have not been taken as required to prevent a recurrence, this will exclude the manufacturer/supplier from the framework.

4.9.2.16 Products are not sold through other NHS Supply Chain frameworks, as this would lead to unnecessary duplication and/or potential conflict.

4.10 Nationally contracted products

4.10.1 Purpose

Nationally Contracted Products (NCPs) are part of the response to the Carter Reports[345], which recommend product range standardisation to remove unwarranted variation, with a

commitment to deliver optimal value for the NHS as a whole through efficiency savings. However, such focused standardisation requires a more rigorous approach to evaluation, and care must be exercised in the selection of NCPs, since this initiative limits user choice, as illustrated by Figure 12. below.

Figure 12. Nationally Contracted Products Require Robust Evidence

4.10.2 Expectations

4.10.2.1 All NCPs must be accompanied by a completed supplementary NCP Product Evaluation Report, as well as the wider Product Evaluation Report at CARF, unless only a single NCP or group of NCPs is under review, in which case the supplementary report alone will suffice.

4.10.2.2 Associated quality and safety concerns should be documented, with a summary of risks and mitigations associated with each concern raised; if risks remain, the product(s) lack suitability for an NCP until all concerns are resolved.

4.10.2.3 Expert stakeholder involvement and liaison will help to identify relevant sources of data intelligence for review, and findings should be summarised; if there has been any recommendation not to use a product, it is not suitable for NCP until all concerns are resolved.

4.10.2.4 NCPs require strong evidence that established industry standards have been identified and met.

4.10.2.5 NCPs require documented evidence that the proposed product or product range represents user requirements.

4.10.2.6 NCPs require alignment to national strategies and expert reference group requirements and priorities.

4.10.2.7 NCPs must only be proposed in products, ranges, or sub-lots with a good track record for quality, i.e. a low number of complaints, recalls, and/or safety alerts.

4.10.2.8 NCPs require alignment with product range and associated components across a framework, lot, and sub-lot.

4.10.2.9 NCPs require robust product specification criteria developed with stakeholders.

4.10.2.10 NCP supplier(s) should be contracted to offer Product Example(s), to support local implementation and switching.

4.10.2.11 Details of the intended product user groups, number of stakeholders involved, their organisations, functions, roles, and evaluation methods used should be summarised for each product, covering all product components, including provision of samples for stakeholders to test within their clinical/live settings.

4.10.2.12 Aside from other means of evaluation as required, all NCPs must be checked by provision of samples for stakeholders to test within their clinical/live settings.

4.10.2.13 MDR and IVDR class should be entered for each NCP, along with the indications for use of the product.

4.10.2.14 For each NCP, all product criteria required as a result of stakeholder involvement must be accompanied by expected fit, form, and function characteristics developed by CTSPs, including specific qualities and measures (e.g. relevant sizes, dimensions, degrees, materials, etc), performance thresholds (e.g. specific break tests, viscosity levels, etc), and permitted deviations and tolerances (e.g. 2 mm +/- range, etc).

4.10.2.15 All product criteria required as a result of stakeholder involvement must be met for CaPA approval; if a decision is taken not to include any product criteria requested by stakeholders, a satisfactory explanation should be provided.

4.10.2.16 Final launch plans should be summarised for each NCP, covering features, benefits, and final specifications - which must incorporate the new product criteria identified as a result of stakeholder involvement (including, where applicable, patients, carers, and others), and clearly defined technical criteria with expected performance thresholds, measures, permitted deviances, and tolerances. Compatibility considerations, awarded suppliers that met the stakeholder product criteria and specification, alternative products and suppliers (for supply chain resilience), availability dates, (including regional and national availability), associated delist and transition plans, accessibility and logistics arrangements should be described, to support development of the NCP Customer Report (i.e. completion of one NCP Customer Report Template per NCP – except for different sizes or colours of the same product - as per Marketing Guidance, with CaPA approval), for all NCPs.

4.10.2.17 A technical evaluation check should be completed for all products to be procured (see section 4.9).

4.10.2.18 NCP Product Examples should be tendered during the procurement process as part of each NCP supplier contract, so that they are available to be shared when NCP Customer Reports are published, for organisations to complete a local impact assessment.

4.10.2.19 CTSPs should schedule a quality assurance webinar to include representatives from CaPA, Marketing, Customer Engagement, and Clinical Nurse Advisors, at two weeks, one month, and six weeks after each NCP launch, to review customer feedback, ensure customer satisfaction, and support NCP quality assurance.

4.11 Product criteria, specification, and suppliers

4.11.1 Purpose

Quality management is user-centric. The supply chain exists to serve the needs of users, maintaining high quality standards, and evolving with the continually changing health and care landscape to create efficiency savings - if users are dissatisfied, for example where products fail, transparent and timely corrective action is required at the whole system level, to prevent a recurrence. The continuous quality management cycle employs a systematic 'Plan, Do, Study, Act' methodology, as illustrated by Figure 13. below, to ensure that user needs are met, quality is controlled and monitored, and quality improvement is continuous.

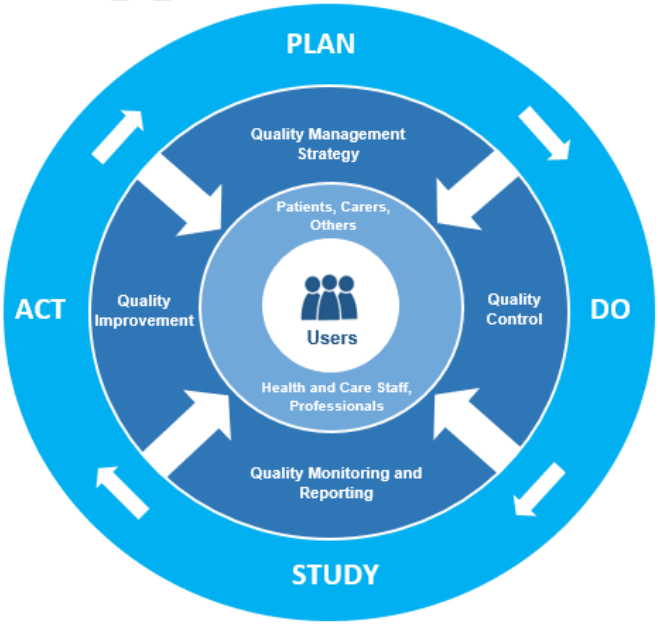


Figure 13. Continuous Quality Management

4.11.2 Expectations

4.11.2.1 Key final product criteria identified by stakeholders as a result of involvement, along with the total number of staff/professionals, and patients, carers, and others (where applicable) involved as stakeholders (demonstrating the breadth of involvement), and final specification(s) (with associated measures, performance thresholds, deviations and tolerances), incorporating the criteria agreed with stakeholders, should be entered by Lot and sub-lot to evidence range optimisation developments.

4.11.2.2 If a decision is taken not to include any product criteria requested by stakeholders, a satisfactory explanation is required for CaPA approval.

4.11.2.3 Suppliers that met the final product criteria and specification agreed as a result of stakeholder involvement, that were awarded, should be listed, along with available alternative suppliers to reduce the likelihood of supply chain interruption.

4.12 Product hierarchy

4.12.1 Purpose

It is essential to declare the final framework name, number of products, and final product hierarchy as a formal record of the final framework agreed and a conclusion to the evaluation report, including Lot Numbers and Names, and Sub-Lot Names, as illustrated by Figure 14. below:

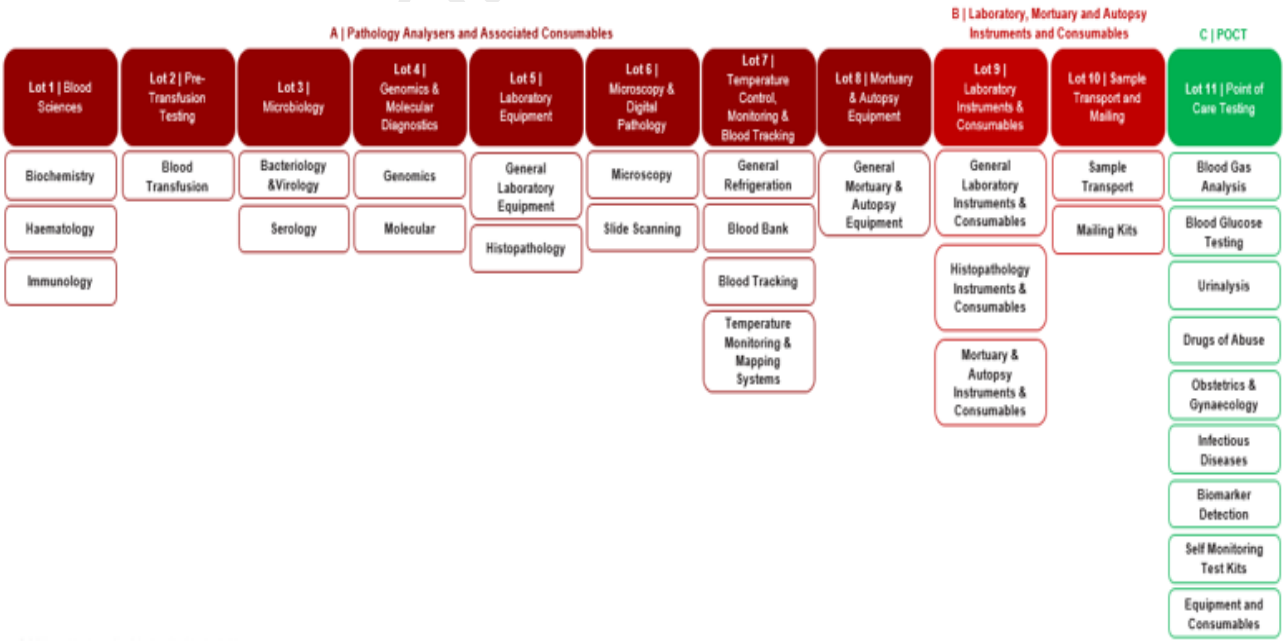


Figure 14. Product Hierarchy

4.12.2 Expectations

4.12.2.1 Add the final framework name – which should be representative of the product hierarchy, and meaningful to users browsing the catalogue.

4.12.2.2 Enter the total number of products on the final framework, minus skews such as different colours or sizes, and for comparison, add the number at last award.

4.12.2.3 Add the final product hierarchy.

4.13 Presentation

4.13.1 All PowerPoint Templates (Category Strategy, Sourcing Strategy, Product Evaluation Report, and NCP Product Evaluation Report) represent formal NHS Supply Chain records in support of the organisational memory, and should be presented to Category Council and CARF, and shared with CaPA, marked as final versions.

4.13.2 Filenames should aid governance and traceability, i.e. Tower, Document, Title, Date, Version Number, Draft/Final, e.g. T5 SS Physiotherapy and Occupation Therapy 110719 V5 Draft.

4.13.3 The CTSP is responsible for ensuring that as formal records, for effective review, all such documents are presented to a professional standard, with entries into Templates legible on screen using bold, size 9 Arial Font, of consistent dark blue or white colour as appropriate, line-spacing 1.0, succinct summaries that are informative on review at Category Council and CARF, all speech bubble guidance removed, and table rows deleted where slide keys and footers begin (go to Layout > Delete > Delete Row).

4.13.4 Aside from “NHS”, abbreviations should be preceded by text in full at first use. Explanatory notes may be added by the CTSP at any point.

4.13.5 All documents submitted should be proof-read and spell-checked before submission to CaPA for review, to ensure clarity of content as a public record.

5 Sourcing Strategy Extension

5.1 A Sourcing Strategy may be presented to CaPA for extension, however this will only be considered if an associated Category Strategy has also been approved.

5.2 Category Council approval by all functions is required via completion of the cross-functional PowerPoint Sourcing Strategy Extensions Template.

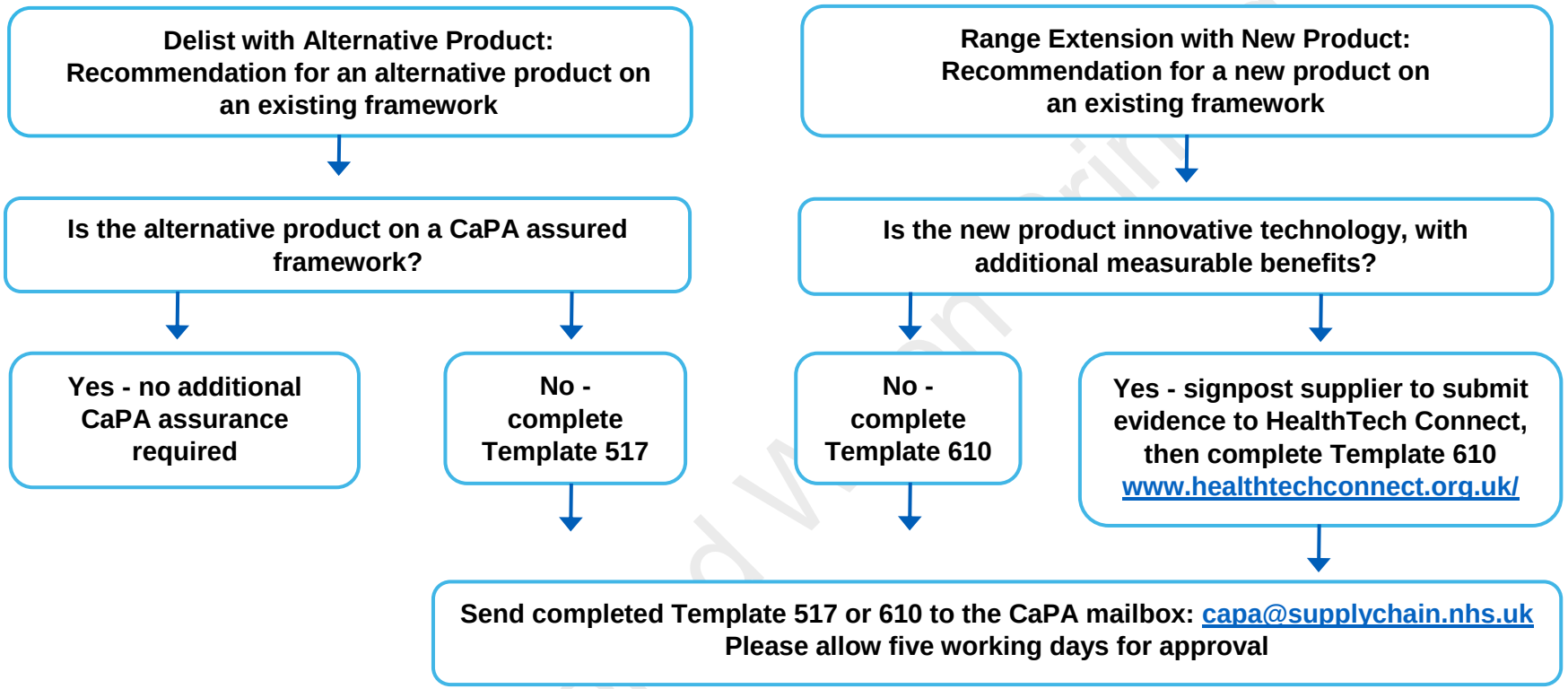
5.3 To ensure there is no breach of public contract regulations, the terms of the existing framework/contract cannot be materially altered.

5.4 CTSPs must answer the following questions for CaPA Framework Extension approval:

Has there been any recommendation not to use any of the products on the framework, e.g. by a National Expert Reference Group?	**If yes, please provide details, and describe the approach taken to address this.**
Have there been any complaints, exceptions, quality issues, MHRA Alerts, Product Recalls, Field Safety Notices (FSNs), Important Customer Notices (ICNs), or NHSI Patient Safety Alerts for any of the products on the framework?	**If yes, please provide details, and describe the corrective action taken to address this and prevent a recurrence.**

6 Mid-Contract Product Replacement (Delist Alternative) or New Product (Range Extension) - CaPA Assurance

6.1 CaPA require evidence of evaluation of products added mid-contract (alternative products for delists, and new products for range extensions), using Excel Templates available from the Data Maintenance team, as illustrated by Figure 15. below and the table that follows:



Keynote:

- Variations of colour and size, delists without alternative products, and delists of duplicate products are exempt from CaPA approval
- Addition of products already approved by CaPA added late to the database due to system error are exempt from CaPA approval
- All products moving on and off live frameworks require evaluation in line with the principles of the wider CaPA Framework

Figure 15. CaPA Mid-Contract Alternative Product (Delist) and New Product (Range Extension) Process

Whilst the following table cannot address every possible scenario, it is intended to support you as a guide when products are delisted and replaced with alternatives, and when ranges are extended with additional new products:

Scenario:	Type of change:	Product on a CaPA assured framework?	Technical standards and certificates checked?	Complaints or quality issues resolved?	Requirements:
Removing a product without an alternative	**Product delist without alternative**	N/A	N/A	N/A	Confirm no clinical need for the product, and no risk of patient harm if unavailable; if clinical need or risk of patient harm exists via a delist, take corrective action, i.e. cease to delist, find an alternative product or extend the range, as per the flowchart above
Existing framework - replacing a product (like for like)	**Product delist with alternative**	No	Yes	Yes	Confirm alternative product is in scope and complete Template 517 for CTM and CaPA approval
Existing framework - replacing a product (like for like)	**Product delist with alternative**	Yes	Yes	Yes	Confirm alternative product listed when framework was CaPA assured, and **if not**, confirm alternative product is in scope and complete Template 517 for CTM and CaPA approval
Existing framework - replacing a product (not the same)	**Product delist with alternative**	No	Yes	Yes	Confirm alternative product is in scope and complete Template 517 for CTM and CaPA approval
Existing framework - replacing a product (not the same)	**Product delist with alternative**	Yes	Yes	Yes	Confirm alternative product listed when framework was CaPA assured, and **if not**, confirm alternative product is in scope and complete Template 517 for CTM and CaPA approval
Existing framework - adding a new product	**Extending product range**	N/A	Yes	Yes	Confirm new product is in scope and complete Template 610 for CTM and CaPA approval
Innovative new product technology (with additional measurable benefits)	**Extend range innovation**	N/A	Yes	Yes	Signpost supplier to submit evidence to HealthTech Connect, confirm new product is in scope, then complete Template 610 for CTM and CaPA approval www.healthtechconnect.org.uk

6.2 Though used less often, an additional Template 615 allows further alternatives to be added after initial delisting with alternatives using Template 517, as it's sometimes necessary to change initial alternatives, e.g. for suspended codes. The same process is followed for CaPA approval of Template 517, as illustrated by Figure 15, using Template 615 instead.

6.3 A further seldom-used, macro-populated Template 518 exists for bulk uploads of 100+ items - completion and approval of an accompanying separate CaPA Template 518 is also required, using the same process for CaPA approval of a Template 610, as illustrated by Figure 15, using Template 518 instead, submitted with the completed macro-populated Template.

6.4 Lastly, an infrequently used Template 545 exists, which covers unit of issue amendment, that can have an associated clinical or storage impact. The same process is followed for CaPA approval of Template 517, as illustrated by Figure 15, using Template 545 instead.

6.5 For non-catalogue range extensions, e.g. capital items, a Word Template 500 Non-Catalogue Extend Range (NCER) Form exists. The same process is followed for CaPA approval of Template 610, as illustrated by Figure 15, using Template 500 NCER instead.

6.6 HealthTech Connect is provided by the National Institute of Health and Care Excellence (NICE), bringing together several organisations to support the development and adoption of innovative technology with additional measurable benefits. There are numerous benefits for suppliers submitting evidence of new product innovative technology to HealthTech Connect, which are listed below:

Supplier Benefits of HealthTech Connect:

- New technology is visible to national decision makers (accessors) via HealthTech Connect
- HealthTech Connect captures the information and evidence accessor organisations need to know about new technology
- For digital technologies, HealthTech Connect links suppliers to standards for demonstrating effectiveness and economic impact
- HealthTech Connect supports efficiency and reduces duplication by providing and sharing information in one place
- HealthTech Connect signposts suppliers to support agencies that can help with funding, evidence generation, and market access

- Suppliers can choose which accessor organisations to share information with via HealthTech Connect, and to change preferences at any time.

7 Appeals

7.1 CTSPs can formally appeal any CaPA assurance decision by submitting an appeal for consideration.

7.2 The CTSP must explain why they do not agree with the CaPA decision and provide necessary evidence to support the review request, submitting the completed Appeals Template in Appendix 2 to CaPA@supplychain.nhs.uk, from which a response will be provided within two working days.

8 Training and Support

Category Tower Managers (CTMs) and Category Tower Service Provider Clinical Teams are expected to undertake CaPA training provided to ensure that assurance framework expectations are fully understood. This Policy will be shared via CTMs for cascade to their teams, controlled via the Q-Pulse document management system, and placed on SharePoint so that it is available to CTSPs. Each CTSP has a dedicated CaPA Product Assurance Specialist (PAS) or Product Assurance Support Officer (PASO), with whom to liaise.

9 Glossary

Category Strategy - The plan to align customer objectives with a strategic approach to maximise value, reduce risk and effectively manage the supply of goods and/or services, through end-to-end management of the supply chain, acute market awareness, sound technical knowledge, and robust stakeholder and supplier relationships.

CE Mark - Indicates conformity with health, safety, and environmental standards for products sold in European Economic Area (EEA).

Exception - An exception request is a type of complaint, where a Trust asks permission not to use a Nationally Contracted Product (NCP) - to justify this they need to explain why the product is not suitable; in liaison with CTSPs, CaPA investigate exception requests related to the clinical appropriateness of the product and respond to the Trust with a decision to uphold or reject the request.

Framework - A procurement framework is an agreement put in place with a provider or range of providers that enables buyers to place orders for services without running lengthy full tendering exercises.

Getting It Right First Time (GIRFT) - A national programme designed to improve the quality of care within the NHS by reducing unwarranted variations.

Healthcare Safety Investigation Branch (HSIB) - An independent organisation funded by the Department of Health and Social Care and hosted by NHS England and NHS Improvement, to improve safety through effective and independent investigations that don't apportion blame or liability.

HealthTech Connect (HTC) - A service provided by the National Institute of Health and Care Excellence (NICE), bringing together several organisations to support the development and adoption of innovative technology with additional measurable benefits.

Human Factors - Psychological principles, such as use of colour and feedback systems, and physiological principles such as ergonomics and fail-safes, in the design of products to ensure they are safe and easy to use.

Innovation - The creation of more effective products and ranges to meet stakeholder requirements where possible.

Integrated Care Systems (ICS) - NHS organisations and local councils in England that have joined forces to coordinate services around the whole needs of each person. Their aim is that people can live healthier lives and get the care and treatment they need, in the right place, at the right time.

In-Vitro Device Regulation (IVDR) Class - A risk level that determines the regulatory assessment route taken for conformity assessment of in-vitro devices: A and B = Low Risk, C = Medium Risk, D and E = High Risk.

ISO 13485:2016 - International Quality Management System (QMS) standard for provision of medical devices and related services that consistently meet customer and regulatory requirements.

ISO 9001:2015 - International Quality Management System (QMS) standard for consistent provision of products and services that meet customer and regulatory requirements.

Medicines and Healthcare Products Regulatory Agency (MHRA) - Regulates medicines, medical devices and blood components for transfusion in the UK.

Medical Device Regulation (MDR) Class - A risk level that determines the regulatory assessment route taken for conformity assessment of medical devices: Non-Medical, Class I = Low Risk, Class IIa or IIb = Medium Risk, or Class III = High Risk.

Nationally Contracted Products (NCPs) - Focused product range standardisation to remove unwarranted variation, with a commitment to deliver optimal value for the NHS through efficiency savings.

National Institute for Health and Care Excellence (NICE) - A Non-Departmental Public Body (NDPB) with responsibility to reduce variation in the quality of care, developing quality standards and technology appraisals, and improving health and social care through evidence-based guidance.

NHS Improvement (NHSI) - A Non-Departmental Public Body (NDPB) with responsibility to support consistently safe, high quality, compassionate, transformed care within local health systems that are financially sustainable.

Primary Care Networks - A key requirement of the NHS Long Term Plan, whereby all general practices sit within a network, to work together at scale supported by local Clinical Commissioning Group (CCG) with recurrent funding to develop and maintain them, to manage financial and estates pressures, to provide a wider range of services to patients, and to more easily integrate with the wider health and care system.

Products - Medical devices, health and care equipment, consumables, and capital items procured and supplied via the NHS Supply Chain.

Sourcing Strategy - A collaborative plan to leverage targeted spend across locations with select suppliers that are best suited to create knowledge and value in the customer-supplier interface, to leverage consolidated purchasing power and find the best possible value in the marketplace.

Sourcing Strategy Extension - An option taken to increase the timescale applicable to a previously approved Sourcing Strategy.

Sustainability and Transformation Partnership (STP) - now Health and Care Partnerships (HCPs) - NHS and local council partnerships covering all of England, working jointly to improve health and social care, run co-ordinated services, agree system-wide priorities, and plan how to improve peoples' day-to-day health and care.

Technical Evaluation - Evaluation to ensure that all products procured comply with required regulatory and safety standards.

Unique Device Identifier (UDI) - A series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. It is made up of two components - a UDI-Device Identifier (UDI-DI) - specific to a manufacturer and a device - and a UDI-Production Identifier (UDI-PI) - which identifies the unit of device production (the DI is also a GTIN - a Global Trade Item Number).

If you have any suggestions for the improvement of this Policy, please email capa@supplychain.nhs.uk.

Appendix 1 CaPA Assurance Framework Template Completion Checklist for CTSPs

To support a consistent and repeatable assurance process and assist CTSPs with Template completion, CaPA have developed this checklist for CTSPs to use prior to submission of Category Strategy, Sourcing Strategy, and Product Evaluation Report Templates to a CaPA Product Assurance Specialist (PAS) or CaPA Product Assurance Support Officer (PASO), for review.

CaPA Assurance Framework Template Completion Checklist for CTSPs	
For CaPA Template Category Strategy, Sourcing Strategy, Extension & Product Evaluation Reports	
1	All CaPA slides present and arranged in order reflective of master CaPA slide pack
2	All CaPA slides fully completed in line with CaPA Policy for CTSPs and all speech bubble guidance
3	“Product hierarchy” includes Lot numbers and names, and Sub-lot names only
4	“Stakeholders involved” includes only those inputting to review of the Framework and/or evaluation
5	All organisation names entered using full legal names for a clear and auditable official record
6	All entries of “Trust”, referring to an NHS Trust, have a capital “T” as this is part of a proper name
7	Email Survey to all known Stakeholders included, to help decide where best to focus product evaluation
8	All Stakeholders listed appear within “Stakeholder involvement” slides, and involvement detailed
9	Stakeholders appearing within “Stakeholder involvement” slides listed as “Stakeholders”
10	All Stakeholder functions listed reflect examples provided within the “Function” speech bubble
11	“Key risks” updated to reflect stage, i.e. removed if fully mitigated by Product Evaluation Report stage
12	“Key risks” completed so that they are appropriate for the public record
13	“Quality and safety concerns” relevant to Framework products fully checked and confirmed
14	For all “Quality and safety concerns”, if none, declaration stated, and other row entries completed N/A”
15	For all “Quality and safety concerns”, “Corrective Actions” entered are specific to Framework products
16	“Data intelligence gathered” includes only findings specific to Framework products and ranges
17	Specific impact of “Data intelligence gathered” findings on Framework products and ranges listed
18	For “Purpose by Lot and evaluation level”, one slide or more completed per Lot per “Product hierarchy”
19	For “Purpose by Lot and evaluation level”, all Sub-lots in “Product hierarchy” entered by Lot
20	For “Purpose by Lot and evaluation level”, slide key used for “MDR/IVDR” and “Evaluation Level”
21	For “Stakeholder involvement”, “Involvement Method Used” matches “Evaluation Level” per Policy table
22	For “Stakeholder involvement”, slide key used for “Involvement Method Used” per Policy table
23	For “Stakeholder involvement”, involvement exceeds minimum where required, per Policy table

24	In “Stakeholder involvement”, dates entered per Sub-lot for involvement undertaken or planned
25	“Range rationalisation and optimisation” reflect findings to date and completed cross-functionally
26	“Nationally Contracted Products” proposed accompanied by completed NCP Product Evaluation Report
27	“Final product criteria, specification, and suppliers” reflect findings to date, completed cross-functionally
28	For “Final product criteria, specification, and suppliers”, one slide or more completed per Lot
29	For “Final product criteria, specification, and suppliers”, all Sub-lots entered by Lot
30	In “Final product criteria, specification, and suppliers”, number of all involved entered per speech bubble
31	In “Final product criteria, specification, and suppliers”, Specification PDFs embedded per Sub-lot
32	In “Final product criteria, specification, and suppliers”, Specification PDFs embedded reflect user criteria
33	“Technical evaluation” includes satisfactory explanation where any response of “No” is provided
34	In “Final product hierarchy”, “Total No. of Products (Minus Skews)” at award and at last award entered
35	All slides proof-read, spell-checked, in bold size 9 Arial font of consistent dark blue or white as required
36	All abbreviations preceded by words in full and contained in brackets when first used in document
37	Capitalisation, and grammar, e.g. full stops used consistently and correctly for a clear official record
38	All Template slides checked to ensure all findings clear and transparent for the public record
39	All Template slides cross-referenced to ensure all entries synchronised with previous stage pack
40	All Template slides cross-referenced to ensure all entries are synchronised across pack
41	Template slide pack page numbering, headers and footers checked and correct

Pack checked and complete? Please email all documents for review to: CaPA@supplychain.nhs.uk, copying in the allocated Product Assurance Specialist - thank you

Appendix 2 Appeals Template

CTM Use	**CaPA Use Only**
CTM:	Date Appeal Submission Received:
CTSP:	CaPA Reviewer:
Date:	Date:
Contact Email:	Contact Email:
Reason(s) for Appeal:	
CaPA Decision:	
Outcome:	
Uphold Appeal? Yes/No	
Date of Appeal Submission Response:	
Date:	