NHS England

Robotic assisted surgery framework agreement call-off guidance

1. Defined terms

In the context of this guidance, the following defined terms apply:

Clinical pathway: a clinical pathway is defined at the procedure level (rather than at specialty level) and refers to a specific surgical procedure characterised by one or more of the following: 1. the anatomical site; 2. the surgical intervention performed; and/or 3. the patient indication. For the purposes of applying justification 1 set out at section 5 ('installed base expansion'), a clinical pathway is a distinct procedure type (for example, radical prostatectomy, partial nephrectomy, hysterectomy), rather than a broader specialty grouping.

Contracting authorities: NHS organisations (including NHS trusts, foundation trusts and other eligible bodies) responsible for procuring robotic assisted surgery systems for the NHS, and for ensuring compliance with applicable procurement legislation and governance requirements.

Effective date: A procurement is considered to have been initiated where a contracting authority has not, prior to the stated effective date, taken substantive steps to engage a supplier in a manner that would reasonably evidence an intention to enter into a contract (including through direct award) under an existing framework agreement.

Framework agreement hosts: Organisations responsible for establishing and managing national framework agreements for robotic assisted surgery systems (including NHS Supply Chain and NHS SBS), supporting compliant call-off processes and providing guidance to contracting authorities.

Direct award: The process of selecting and awarding a contract to a supplier without running a competition (either from the market or within a framework agreement), where the contracting authority determines the supplier in accordance with the rules of the relevant agreement or legislation.

Call-off: A framework agreement call-off (or call-off contract) is a contract between a contracting authority and a supplier that is awarded under the terms of an existing framework agreement.

Further competition: A further competition is a procurement process where a contracting authority invites all eligible suppliers on a framework agreement (or specific lot) to bid for a specific requirement.

2. Purpose

Purpose: This document sets out NHS England guidance to support consistent and proportionate application of direct award provisions for robotic assisted surgery procurements. It does not replace contracting authorities' statutory obligations or existing framework agreement terms but sets an expected approach to decision-making for new robotic assisted surgery procurements.

Audience: Framework agreement hosts for NHS robotics categories and contracting authorities using those frameworks.

3. Objective

This guidance is intended to support the development of a competitive, sustainable and resilient robotic assisted surgery market. Given the long-term nature of robotic assisted surgery investments and the significant operational, clinical and commercial dependencies that can arise once a platform is established, procurement decisions should promote healthy markets while ensuring the NHS secures value for money and the best possible outcomes for patients.

This guidance establishes competition as the default route for call-offs, restricting direct awards to clearly defined circumstances with clear governance and transparency. The objective is to secure value for money, drive innovation, strengthen market resilience and supplier diversity in line with NHS growth ambitions.

4. What is changing?

From 1 September 2026, this guidance applies to the procurement of new robotic assisted surgery systems where the procurement has not already been initiated before that date, in accordance with the definition of effective date. This applies irrespective of the source of funding, including where funding is provided in whole or in part by a charity, donation, or other third party.

- Further competition should be the default route for robotic assisted surgery purchasing under national framework agreements.
- We expect contracting authorities to procure all new robotic assisted surgery programmes and all new clinical pathways competitively and not through direct award, unless the narrow exemption criteria set out in section 5 are met.
- Direct awards should be limited to the specific circumstances defined in this document and should be clearly evidenced in line with the guidance below;

proposals for a direct award should be submitted to NHS England for consideration and approval.

- Governance and transparency are strengthened through ongoing monitoring, assurance, and quarterly reporting to the NHS England National Steering Committee for Robotically Assisted Surgery, on all direct awards and overall route-to-market mix.

5. When a direct award may be appropriate

Our guidance is that a direct award under a framework agreement is appropriate only if one of the following justifications applies and is supported by auditable evidence.

Meeting one of the criteria below does not require a contracting authority to make a direct award; it simply means that a direct award may be considered, where this is supported by the required evidence and remains compliant with the relevant framework agreement requirements.

	Scenario (when a direct award may be justified)	**Rationale**	**Minimum evidence to document**
1.	Installed base expansion limited to the scope of existing clinical pathways* and cannot be used to justify broader system roll-out (additional sites) or new clinical pathways.	Avoids material cost-of-change when expanding capacity of existing systems.	Current installed base and utilisation data (including HES Data and procedures currently performed); quantified cost of change including benchmarking comparison; clinical service impact assessment and business case for extension of programme.
2.	Genuine urgency or continuity of care (safety or critical service risk) for existing robotically assisted clinical pathways, arising from unforeseeable events only. (non-renewable maximum 12 months)	Immediate replacement or continuity needed to avoid service interruption or patient safety risk in response to, for example, unanticipated equipment failure or patient-safety incidents.	Incident or service risk log; clinical safety and service impact assessments; statement from the chief financial officer that no further extensions will be permitted beyond 12 months.
3	Time-limited bridging arrangement (rental, pay per use, lease) to support continuation of existing robotically assisted clinical pathways, where a defined group of trusts is actively working to aggregate demand ahead of a future competitive procurement.	Keeps services running before a full competition (for example, to align multiple trusts or an ICS pipeline).	Pipeline plan and re-procurement timetable.

	Scenario (when a direct award may be justified)	Rationale	Minimum evidence to document
4	Single-supplier capability for a narrowly defined, evidence-based requirement	Only one supplier demonstrably meets specific, defensible clinical or operational needs (for example, specific clinical requirements), which cannot be met by for example, alternative CE-marked devices.	Independent clinical input (requiring ratification through the NHS England National Steering Committee for Robotically Assisted Surgery; confirmation that all credible suppliers have been given a defined opportunity to demonstrate capability (right of reply window).

* Refer to the defined terms section above for the definition of clinical pathway. Direct award cannot be used to introduce robotic assisted surgery into new specialties or to expand a robotic assisted surgery programme beyond the scope justified. Any such expansion requires a competitive process.

For the avoidance of doubt, contracting authorities are encouraged to use national framework agreements whenever these are available and suitable for their needs. It is essential that contracting authorities take responsibility for ensuring any further competitions are conducted in accordance with the relevant framework agreement and applicable procurement regulations. If using a national framework agreement is not possible, authorities may opt for open procurement. However, they must still ensure all procurement activity complies with the requirements set out in the Procurement Act 2023.

6. Minimum process before a direct award is made

- Completion of a direct award justification form (appendix 1) and requisite evidence to support the justification ground, as set out in section 5.
- Conflict of interest declarations from decision-makers and clinical leads; records retained.
- Sign-off: clinical director (clinical case), chief finance officer (value for money or affordability), procurement lead (process compliance).
- Notification and submission of the justification form and evidence by the contracting authority to the NHS England Commercial Spend Controls Team for direct award call-offs. 15 working days should be allowed for NHS England queries, assessment and approval before any contract award. Send to england.commercialsc@nhs.net and copy in the relevant framework host.

7. Governance, monitoring, and assurance

Framework agreement hosts will support the implementation of this guidance through framework tools, active framework management, and engagement with contracting

authorities, recognising that ultimate accountability for procurement decisions and compliance with these guidance requirements rests with the contracting authority.

7.1 Proportionate oversight and alignment with guidance requirements

Framework hosts will operate proportionate oversight arrangements in relation to robotic assisted surgery call-offs, with the objective of promoting competition as the default route to market. This should include:

- buyer guidance and communications, and engagement with contracting authorities where a direct award is proposed or used
- quarterly reporting by framework agreement hosts to the NHS England National Steering Committee for Robotically Assisted Surgery, covering for each award: contracting authority; framework or lot; date; supplier or platform; route (further competition or direct award); brief justification (direct award only); contract value and term

7.2 Records and audit evidence

Contracting authorities remain accountable for maintaining a complete and auditable record of all robotic assisted surgery procurement decisions, including the rationale for the selected route to market, required approvals, and contract documentation.

8. Appendix 1: Direct award justification template

1. How to use this template

This document is to be used in conjunction with the Robotic Assisted Surgery Framework Agreement Call-Off Guidance and should be completed when a further competition through a framework is not being followed, and the proposal is to make a direct award.

Direct awards from framework agreements can only be made in compliance with the framework schedules and the relevant procurement legislation which governs the framework agreement (for example, the Public Contracts Regulations 2015 or the Procurement Act 2023).

All sections of this form must be completed and relevant sign-off must be gained ahead of awarding a contract through direct award.

This template, alongside evidence and approval attachments, should be sent by the contracting authority to NHS England (england.commercialsc@nhs.net) and the relevant

framework agreement host, for audit purposes, allowing 15 working days for queries, validation and approval before contract award.

2. Project information

Project information required	Project information response
Project title	[insert project title]
Workplan reference	[insert contract or workplan reference]
Estimated contract value	[insert estimated contract value]
Contracting authority	[insert contracting authority name]
Framework agreement host name	[insert framework host and framework name]

3. Rationale for Direct award including market assessment

Rationale and market assessment
Set out the rationale and supporting market assessment underpinning the decision to use a direct award. The market assessment should summarise engagement activity, including the approach taken and indicative dates.

4. Direct award justification

Provide the justification for **not** following a competitive process.

Ref	Scenario		Justification
1	Installed base expansion limited to the scope of existing clinical pathways	☐	
2	Genuine urgency or continuity of care (safety or critical service risk) for existing robotically assisted clinical pathways, arising from unforeseeable events only.	☐	

3	Time-limited bridging arrangement (rental, pay per use, lease) to support continuation of existing robotically assisted clinical pathways, where a defined group of trusts is actively working to aggregate demand ahead of a future competitive procurement.	☐	
4	Single-supplier capability for a narrowly defined, evidence-based requirement	☐	

5. Cost of change

Cost of change summary
Provide breakdown of the cost of change including supplier impact and service delivery.

6. Approval to award

All named roles below must approve the commercial approach. Please attach evidence of approval.

Role	Approver name	Approval date
Clinical Director	[insert name]	[insert date]
Chief Financial Officer	[insert name]	[insert date]
Procurement Lead	[insert name]	[insert date]

Date of issue to NHS England england.commercialsc@nhs.net and relevant framework agreement host	[insert date]

Please allow 15 working days for any queries, before contract award.

7. Evidence of approval

Include evidence of approval

For the avoidance of doubt, the contracting authority remains responsible for ensuring that all procurement activity is undertaken in line with relevant legislation, regulation, policy and framework agreement requirements.