Cost recovery for Technology Appraisals (TA) and Highly Specialised Technologies (HST) – 2023-24 review

# Executive summary

1. In response to the [2018 Department of Health and Social Care (DHSC) consultation on NICE technology appraisal and highly specialised technologies work programme (charging and appeals)](https://assets.publishing.service.gov.uk/media/5c0a7da340f0b6706e13b49d/government-response-to-nice-recommendations-consultation.pdf), a commitment (section 6.4) was made to monitor the impact of the charges in the first year and formally review the charging regime at the end of the second year and after as required.
2. Annual reviews of the cost base and inflationary uplifts to the fees were applied in years 3 (2022-23) and 4 (2023-24). In addition to reviewing the cost base and fees, the 2023 review considered the structure, mechanism, and application of charging.
3. NICE is in year 4 of [charging for Technology Appraisals (TA) and Highly Specialised Technologies (HST)](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/charging/procedure-ta) and is yet to achieve full cost recovery. The deficit has reduced each year, but we need to close the gap to comply with [HM Treasury’s guidance, Managing Public Money (MPM)](https://www.gov.uk/government/publications/managing-public-money), and secure the programme's financial sustainability.
4. [NICE is transforming](https://indepth.nice.org.uk/transforming-nice/index.html) to meet the changing health and care system needs to maintain its role in helping the NHS deliver the most effective and affordable healthcare. NICE aims to deliver more relevant, timely, useable, and impactful guidance. To support this the TA-HST work programme must operate sustainably and efficiently, allowing efficient responses to life science developments. To keep pace with the scale of change and ensure that charges are accurate, the cost recovery mechanism and principles must be adjusted to reflect current processes and practices.
5. The review's findings have been considered in the context of the regular NICE business planning cycle. For the 2024-25 business year, the fees for TA-HST guidance evaluations will increase by 23%, (see [fees for 2024-25](#_Fees_for_2024-25)).
6. This consultation paper includes proposals that affect the charging mechanism for TA-HST. They are:
7. Confirming evaluation timelines and commitment to pay
8. Introduction of a change fee
9. A charge for technical engagement
10. The charge for pilot topics and amendments to processes
11. Updates to refund procedures
12. The consultation focuses on eliciting stakeholders' feedback on the proposals as laid out in sections 25 – 61.
13. We will not be asking for comment on the new fees for 2024-25 ([appendix 2](#_Appendix_2_-)). Section 13 - 24 provides the background to the changes which is essential for stakeholders to understand.

# Introduction

1. In April 2019, the transfer of costs to the life sciences industry through [a charge for guidance development and publication](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/charging/procedure-ta) was implemented. The transfer was to enable NICE to stabilise its financial position. In the 4 years since its implementation, NICE has been unable to recover its costs within each financial year. This is even more pertinent to manage in a challenging fiscal environment and as per the [Health and Social Care Act 2012](https://www.legislation.gov.uk/ukpga/2012/7/contents), NICE must exercise its functions effectively, efficiently, and economically.
2. The processes and methods for producing TA-HST guidance recommendations are routinely updated. Any review includes extensive engagement with the life sciences industry, other interested parties, and public consultation. In January 2022 the [NICE health technology evaluations: the manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) was published along with the [NICE health technology evaluation topic selection: the manual.](https://www.nice.org.uk/process/pmg37/chapter/about-this-guide) The former was updated on 31 October 2023 to reflect the new [proportionate approach to TA processes](https://www.nice.org.uk/about/what-we-do/proportionate-approach-to-technology-appraisals). NICE now operates several different processes for the development of TA-HST guidance:
* Single Technology Appraisal (STA) and Highly Specialised Technologies (HST)
* Cost comparison (CC)
* Rapid Review (RR)
* Multiple Technology Appraisal (MTA)
1. In accordance with [UK Statutory Instrument 2018 No.1322](http://www.legislation.gov.uk/id/uksi/2018/1322) and [HM Treasury’s guidance, Managing Public Money (MPM)](https://www.gov.uk/government/publications/managing-public-money), NICE must recover the total cost of the guidance development for a TA or HST from the company that expects to market the technology in England.
2. NICE must recover all costs associated with the evaluation in accordance with existing processes. In line with [IFRS 15 Revenue from Contracts with Customers](https://www.ifrs.org/issued-standards/list-of-standards/ifrs-15-revenue-from-contracts-with-customers/), income is recognised as and when key milestones are completed. To provide an illustrative example, the key milestones included in the charge for an STA are:
3. Horizon scanning, topic selection, scheduling, and scoping
4. Invitation to participate
5. Evidence submission
6. External assessment report delivery
7. 1st committee meeting
8. 2nd committee meeting
9. Final draft guidance
10. Guidance publication

# Fees for 2024-25

1. In line with [HM Treasury’s guidance, Managing Public Money (MPM),](https://www.gov.uk/government/publications/managing-public-money) NICE has reviewed the cost of making TA-HST recommendations. The charges are based on actual expenditure, including direct, indirect, and overhead costs.
2. MPM sets out the main principles for dealing with resources in the UK public sector. This includes the principles for setting fees ([HM Treasury’s guidance, Managing Public Money (MPM), Chapter 6](https://www.gov.uk/government/publications/managing-public-money)). Some of the basic principles applied are:
* Set charges to recover full costs (direct, indirect costs, and overheads).
* Set fees to neither profit at the expense of consumers, nor make a loss for taxpayers to subsidise.
* Control costs as if the costs were funded by the taxpayer.
* Normally require and rely on legislation by ministers (in NICE’s case Statutory Instrument 2018 No: 1322).
1. Over the last 2 years, inflationary changes have required an uplift in the fees (predominantly due to centrally set pay awards) and have not gone far enough in successfully managing NICE’s deficit.
2. During the review, we have used the full cost methodology (as described in [HM Treasury’s guidance, Managing Public Money (MPM),](https://www.gov.uk/government/publications/managing-public-money) and considered the following:
* Cost base (direct, indirect, and overhead costs)
* Unit capacity and utilisation
* Review of trends in previous years (volume and activity)
* NICE-wide resources involved in guidance production
* Inflationary pressures
* Tracking internal timesheet data
1. Table 1 shows the current fees (introduced on 1 April 2023) and those effective from 1 April 2024. Table 2 outlines the changes in the direct and indirect costs and overheads, as well as the expected units of work between 2023-24 and 2024-25.

Table 1 – current and proposed fees

|  |
| --- |
| Standard fees |
| Process | Unit | Current fees (£) | Proposed fees from 1 April 2024 (£) | % Increase |
| Single Technology Appraisal/Highly Specialised Technologies (STA-HST)\*\*includes streamlined STA | 1.0 | 151,700 | 186,100 | 23% |
| Cost Comparison/Rapid Review (CC/RR) | 0.7 | 106,200 | 130,300 | 23% |
| Multiple Technology Appraisal (MTA) – Standard | 1.5 | 227,600 | 279,200 | 23% |
| Multiple Technology Appraisal (MTA) – Complex | 2.0 | 303,400 | 372,200 | 23% |
| **Small company fees – 75% discount** |
|  | **Unit** | **Current fees (£)** | **Proposed fees from 1 April 2024 (£)** | **% Increase** |
| Single Technology Appraisal/Highly Specialised Technologies (STA-HST)\*\*includes streamlined STA | 1.0 | 37,925 | 46,525 | 23% |
| Cost Comparison/Rapid Review (CC/RR) | 0.7 | 26,550 | 32,575 | 23% |
| Multiple Technology Appraisal (MTA) – Standard | See standard fees.Charges are split between participating companies and the 75% discount applies to any participating small companies. |
| Multiple Technology Appraisal (MTA) – Complex |

Table 2 – key changes to fees

|  |  |  |
| --- | --- | --- |
| Costs (£000) | 2023-24 | 2024-25 |
| Direct costs | 8,575 | 9,387 |
| Indirect costs | 2,426 | 3,113 |
| Overhead | 1,967 | 2,389 |
| **Total costs** | **12,968** | **14,889** |
| **Volumes (units)** | **85.5** | **80** |
| **Charge (STA)** | **151.7** | **186.1** |

1. [Appendix 1](#_Appendix_1_-) describes the NICE teams included in the direct and indirect costs and the functions contributing to overheads.
2. The factors influencing and driving the fee increase include:
	1. A higher-than-expected [NHS pay award](https://www.nhsemployers.org/payofferFAQs) granted in 2023-24. An assumed 3% pay award was built into the 2023-24 prices; this was later confirmed to be 5%. NICE absorbed the additional 2% in 2023-24. The decision to absorb the extra cost was taken due to the timing of the NHS pay award and it was agreed that it would not be appropriate to increase prices mid-year. At the time, NICE clarified that this increase would be reflected in the fee from 2024-25 onwards. A pay award of 4% has been assumed for the 2024-25 fees.
	2. Included in fees for the first time:
		1. Medicines Optimisation Team – majority to support cost comparison activity, pathways and STAs.
		2. [Science Policy and Research Team](https://www.nice.org.uk/about/what-we-do/our-research-work) – modular updates and broader research and methods related to TA and HST activity only.
	3. The provision and delivery of the TA-HST programme in their totality and the requirement to reflect the resources required to develop modular updates and associated changes to methods and processes. This includes the proportionate approach activity, for example cost comparison and pathways pilots.
3. When reviewing the fees, NICE must also consider the capacity of the work programme. The projected total for 2024-25 is 80 units, based on a combination of previous year’s actuals and forecasted demand in 2024-25 (considering horizon scanning, availability of committee slots and external assessment group capacity). The expected capacity has been revised to ensure that the capacity in place reflects the level of demand and that the fees are set at a level that allows the programme to recover all costs.
4. The work programme delivers the 80 units flexibly, comprising several process types. It is important to emphasise that 80 units do not directly correlate to the number of guidance publications per year.

## Considerations for future costs (not included in the 2024-25 fees)

1. By the end of 2023-24, NICE aims to have aligned methods and processes between the clinical guidelines and TA-HST programme, with an interim process published. The cost of incorporating TAs into guidelines will be reviewed at this point.
2. NICE committee members require adequate remuneration to facilitate their availability to attend and contribute to guidance development. There will be an increase in the rate of committee members that will receive renumeration in 2024-25. It is proposed that this will be absorbed into the work programme during 2024-25 but will require a later review.
3. NICE's pension contributions are set to increase from 1 April 2024. This hasn’t been factored into the 2024-25 fees but will be included in the future.

# Proposals for consultation

1. The review has considered all aspects of guidance development and the interface with cost recovery. The following proposals have been developed to support the aim of achieving full cost recovery and securing the financial stability of the TA-HST work programme. Stakeholders are asked to provide feedback on:
2. Confirming evaluation timelines and commitment to pay
3. Introduction of a change fee
4. A charge for technical engagement
5. The charge for pilot topics and amendments to processes
6. Updates to refund procedures

## Background - the impact of scheduling changes

1. NICE must recover opportunity costs when planned resources are not utilised. NICE cannot produce a consistent cost recovery forecast due to company-driven changes to topic scheduling created by updates to regulatory timelines and company submission plans. This creates instability and difficulties in managing and planning resources for the work programme. Resources allocated to a topic (NICE staff, external assessment groups, committee slots) can be lost if insufficient notice is given, as they cannot be reallocated to another topic.
2. The following has been analysed:
* The process of invoicing - seeking opportunities for NICE process efficiency gains
* The impact of timeline changes - movements in the work programme schedule
* Cost recovery for topic selection, scheduling, and scoping
* Lost opportunities for internal and external resource capacity
1. Currently, to secure payment for the evaluation NICE requests a Unique Reference Number (URN) from the company approximately 3 months before the Invitation to Participate (ITP) is issued. Invoice payment is required by the evidence submission deadline.
2. As per the [NICE health technology evaluation manual (section 5.2.4](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation)), the scheduling of topics into the NICE work programme is managed using information received from the company on expected MHRA regulatory approval dates and submission readiness. NICE seeks this information from companies at several points before evaluation timelines are confirmed. The Topic Selection team facilitates communications regarding scheduling timelines with the Scheduling Technologies and Regulatory Timelines (START) form.
3. ‘Optimal’ topics are scheduled in parallel with the anticipated MHRA marketing authorisation dates and final guidance is expected within 90 days of GB MA. Companies are asked to confirm submission timelines ahead of the start of scope development.
4. However, the company may prefer to submit to NICE on a later alternative submission timeline. These are scheduled as ‘divergent’ topics and will not be timely (i.e., published within 90 days of GB MA). The reasons for divergent topic scheduling can be seen in the formal [integrated performance report](https://www.nice.org.uk/Media/Default/Get-involved/Meetings-In-Public/Public-board-meetings/september-23-pbm-IPR-september-23.pptx) presented to the NICE board in September 2023.
5. Figure 1 shows the current charging mechanism, associated timelines and the topic selection, scheduling, and scoping stages. Guidance publication is assumed at month 0.

Figure 1 – charging mechanism

 

1. The scheduling team monitors the number of topic movements in the work programme. In the period April to October 2023, 41% of scheduling changes were related to a licencing change, and 37% were through company requests. These changes create a tension between achieving full cost recovery and planning the work programme to meet timeliness targets.
2. Table 3 provides a summary of the topic scheduling changes for the current business year 2023-24.

Table 3 – topic scheduling changes for 2023-24

|  |  |  |  |
| --- | --- | --- | --- |
| Month | Company request | Licencing change (MHRA) | Other |
| Apr-23 | 11 | 10 | 22 |
| May-23 | 16 | 19 | 5 |
| Jun-23 | 9 | 11 | 5 |
| Jul-23 | 19 | 14 | 11 |
| Aug-23 | 18 | 11 | 2 |
| Sep-23 | 11 | 7 | 4 |
| Oct-23 | 7 | 29 | 4 |
| **Total** | **91** | **101** | **53** |
| % of total | 37% | 41% | 22% |

### Proposal 1 – Confirming evaluation timelines and commitment to pay

1. The topic selection stage determines whether a topic will be selected for evaluation and at this point companies are informed of the proposed NICE submission dates. The company will be required to signal their preference for optimal (aligned to marketing authorisation dates) or divergent scheduling (aligned to the company's preferred NICE submission date) when completing the START form.
2. Upon receipt of the START form the scheduling team will plan scoping and evaluation timelines based on the company's preference. Once a company confirms in writing they accept the evaluation timelines including the ITP date and submission deadline, they will be asked to provide a URN. The URN demonstrates a commitment to the agreed timelines and to pay the associated charge. The URN must be received for the timeline to be confirmed within the NICE work programme.
3. By advancing this step in parallel with confirming evaluation timelines, NICE will drive forward a more predictable work programme to better inform financial forecasting, reporting, and resourcing. This change will also positively support the financial planning cycle for companies. There is no change to when the invoice is issued and payment will continue to be required by the submission deadline.
4. Figure 2 shows the proposed changes to the charging mechanism and associated timelines for charging and the topic selection, scheduling, and scoping stages. Guidance publication is assumed at month 0.

Figure 2 – proposed changes to the charging mechanism



### Proposal 2 – introduction of a change fee

1. To address the impact of topic rescheduling and to recover lost opportunity costs, NICE proposes implementing a change fee. The change fee will apply after the company has confirmed the evaluation timelines, in the following scenarios.
* A company request to change the timelines
* There are regulatory delays
* A company no longer wishes to provide a submission for the evaluation.
1. This will allow NICE to recover costs when resources have been allocated and not utilised. Resources include planning and operations functions such as topic selection, scoping and allocating NICE staff and committee slots.
2. Regarding a request to change timelines or regulatory delays, the change fee will be set at £18,610 for 2024-25 charges. If the company no longer wishes to provide a submission, NICE will confirm the fee once it has considered the resource effort utilised on the topic.
3. The URN provided by the company when evaluation timelines are confirmed will be utilised to recover the change fee.
4. In all scenarios, payment will be required from the company before final guidance is published.
5. The change fee will not apply if.
* An ITP has been issued. In this case, the refund process will be followed.
* NICE initiates the change to timelines.

## Background - technical engagement

1. In April 2023, the technical engagement step was removed as a standard point in the TA process, as it did not meet its aims of achieving topics to have final guidance produced at the first committee meeting.
2. The recently updated [NICE health technology evaluations: the manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) describes the decision to use the technical engagement step as follows:
* 5.7.2 Technical engagement will only be included if NICE considers that it is appropriate, helpful, and proportionate, taking into account whether the technical engagement process is likely to resolve key issues before the committee meeting,
* 5.7.3 If technical engagement is included, timelines will be amended to allow for engagement time with stakeholders
1. The technical engagement stage is not included in the charge for a TA or HST. The step is helpful for some evaluations but is not always necessary or proportionate.
2. In practice, all evaluations scheduled between 1 April 2022 and 3 March 2023 had technical engagement included by default, and this step was only removed in a small number of cases. This means that some evaluations included this step when it was unnecessary; this was regarded as a non-recoverable unit of activity.
3. As described above, processes have been refined, and technical engagement will only be added when it adds value by resolving key issues ahead of the committee meeting. This ensures it is only used when it can aid efficient decision-making and contribute to retaining rapid access to clinically and cost-effective medicines.

### Proposal 3 – a charge for technical engagement

1. If NICE decide that technical engagement is required to support a topic's progression and to recuperate all costs associated with the evaluation, the exceptional charge for technical engagement will be fixed at 5% of the STA charge, and payment will be required from the company before final guidance publication.

## Background - test and learn of new processes

1. To deliver NICE’s transformation plan and produce relevant, timely, useable, and impactful guidance, there is sometimes a need to pilot new approaches and working methods. The Proportionate Approach to Technology Appraisals (PATT) has developed and continues to evolve, new processes and methods to deliver the ambitions of the transformation plan.
2. For example, new treatments for similar disease areas are increasing, nearly half of TAs are in only 10 disease areas. PATT is developing a ‘pathways’ approach to TA’s, currently in its pilot phase. Pathways aims to combine several appraisals within a single disease pathway, such as renal cell carcinoma and non-small cell lung cancer (both subject to the current pilots).

### Proposal 4 – the charge for pilot topics and amendments to processes

1. Where guidance evaluations are delivered via a pilot, topics will be subject to an divergent fee. For example, ‘pathways’ topics will have a different fee during the pilot phase. Should ‘Pathways’ become a standard business-as-usual approach the fee will be written into charging procedures. In this scenario, we expect the fee to be no more than the largest or lowest fee set out within the [NICE charging procedures.](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/charging)
2. In some cases, NICE may have an opportunity with agreement from the company to amend standard processes. In these cases, a different fee will be explored assessing the resource and unit capacity to be utilised. In this scenario, we expect the fee to be no more than the largest or lowest fee set out within the [NICE charging procedures.](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/charging)

## Background - refunds

1. The current [NICE charging procedures](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/charging/procedure-ta#refunds) state that NICE will fully or partially refund the charge of the evaluation if:
* A single technology appraisal (STA) is converted into a cost comparison appraisal (CCA). In this case, NICE will refund the difference in charge.
* In the sole opinion of NICE, NICE is unable to complete the appraisal after it has started (for example, if the technology does not receive regulatory approval or the company withdraws an application from the relevant regulatory authority). NICE will refund the amount paid, less any costs incurred during the appraisal process up to that point (including fair allowance for overheads and other similar costs).
* The evaluation is delayed and rescheduled more than six months later than the original invitation to participate (ITP) date. NICE will refund the amount paid and recharge at the appropriate rate and time. This helps with managing public monies appropriately, in line with financial regulations and NICE schedules.
* Where an evaluation has required substantially different resource to that of a standard evaluation, alternative refund models may be explored by NICE using a methodology consistent with Managing Public Money.
* All refunds are subject to a standard administration charge. The administration charge allows NICE to recover the administrative costs related to staff and SBS resource used to raise and complete the refund. The administration charge for non-small companies is £100 per refund. Small companies receive a 75% discount, the fee is £25 per refund.
1. For the review, we have considered.
* The current refund processes
* The key milestones included in the charge
* The impact of guidance stopping on achieving full cost recovery

### Proposal 5 – updates to refund procedures

1. Currently, there is no eligibility for a refund once a company has submitted to NICE and the submission review has started. The procedures will be updated to allow companies the opportunity to receive a proportionate refund depending on the key milestones met, resource and unit capacity used. However, once the External Assessment Report has been completed, a refund will not be applicable.
2. Consideration has been given to the impact of rescheduling timelines on cost recovery and future forecasting, as described in [proposals](#_Proposal_1_–) 1 and 2, where a change fee will apply. Depending on the payment status, NICE will refund the amount paid minus the change fee where topics are rescheduled more than four months after the agreed ITP date, and a new URN will be requested once the timelines for the re-scheduled dates are agreed.
3. In recognition of introducing and implementing new processes in April 2023, when an STA follows the streamlined committee decision process, NICE will issue a proportionate refund, less any costs incurred during the evaluation process.
4. All refunds will continue to be subject to a standard administration charge of £100 and £25 for small companies eligible for the discount.
5. [Appendix 3](#_Appendix_3_-) describes the proposed changes to the refund procedures in full.

## Proposals considered but not progressed

1. The review also considered alternative approaches to the charging mechanism; these were dismissed as unfavourable options to implement and proceed.
2. The feasibility of issuing multiple invoices to recover costs during guidance development was examined. This proposal considered whether it would be possible to charge companies the lowest fee (the cost comparison/rapid review fee) and issue a further invoice pre-guidance publication to recover the remaining costs. However, as the work programme primarily consists of standard STA evaluations, this would create a significant burden and cost to administer and require funding via an increase in direct and overhead costs.
3. Similarly, the feasibility of offering a phased payment option to all companies (not just to small companies) was considered. This would create a significant burden and cost to administer and require funding via an increase in direct and overhead costs.

# Appendix 1 - Table of direct, indirect costs, and overheads

\*Included in charges from 24/25 for the first time

|  |  |  |  |
| --- | --- | --- | --- |
|  | Direct costs | Indirect costs | Overheads |
| What | Costs directly incurred and controlled by the TA-HST programme  | Costs incurred by support teams essential to TA-HST guidance delivery | A proportion of back office and estates costs allocated to TA-HST activity |
| Who(Teams) | * Appraisals / Highly Specialised Technologies
* Topic Selection
* Commercial Liaison
 | * Resource Impact Assessment
* Public Involvement
* Editorial and Publishing
* Information Services
* Communications
* Medicines Optimisation\*
* Science policy and research\*
 | * Estates
* Finance and Procurement
* Human Resources
* Digital and IT
* Corporate function
 |
| How | Based on budgeted costs (mostly headcount and committee costs) | Based on apportionments and allocations, derived from information provided by support teams on activity directly attributable to TA-HST | The total costs of the above functions are divided by FTE to give an overhead charge to apply to direct and indirect costs. |
| How much | 63% | 21% | 16% |

# Appendix 2 - Overview of fees for 2024-25

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Single Technology Appraisal (STA) or Highly Specialised Technologies \*includes streamlined STA | Cost Comparison (CC) or Rapid Review | Multiple Technology Appraisal (MTA) standard – up to 3 technologies | Multiple Technology Appraisal (MTA) complex – more than 3 technologies |
| Charge | £186,100 | £130,300 | £279,200 | £372,200 |
| Change fee (if required) | £18,610 | £18,610 | £18,610 | £18,610 |
| Inclusions (Key milestones)  | * Topic selection, scheduling, and scoping
* Invitation to participate
* Evidence submission
* External assessment report
* 1st committee meeting
* 2nd committee meeting
* Final draft guidance
* Guidance publication
 | * Topic selection, scheduling, and scoping
* Invitation to participate
* Evidence submission
* External assessment report
* Panel review
* Final draft guidance
* Guidance publication
 | * Topic selection, scheduling, and scoping
* Invitation to participate
* Evidence submission
* External assessment report
* 1st committee meeting
* 2nd committee meeting
* Final draft guidance
* Guidance publication
 | * Topic selection, scheduling, and scoping
* Invitation to participate
* Evidence submission
* External assessment report
* 1st committee meeting
* 2nd committee meeting
* Final draft guidance
* Guidance publication
 |
| Additional/Differential charges | * Technical engagement
* Pilot topics
* Process amendments
 | * Pilot topics
* Process amendments
 | * Pilot topics
* Process amendments
 | * Pilot topics
* Process amendments
 |

# Appendix 3 - Updated wording for refund procedures

1. NICE will fully or partially refund the charge of the evaluation if:
	1. A single technology appraisal (STA) is converted into a cost comparison (CC). In this case, NICE will refund the difference in charge. See 5.8.27 [NICE health technology evaluations: the manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) for further details.
	2. A single technology appraisal (STA) follows the streamlined decision-making process. In this case, NICE will issue a proportionate refund.
	3. In the sole opinion of NICE, the evaluation cannot be completed after the evaluation has started (for example, if the technology does not receive regulatory approval or the company withdraws an application from the relevant regulatory authority), a proportionate refund will apply for the amount paid less any costs incurred during the evaluation process up to that point (including fair allowance for overheads and other similar costs).
	4. The timelines for the evaluation are rescheduled to more than 4 months later than the agreed original invitation to participate (ITP) date. NICE will refund the already paid amount minus the change fee and formally recharge at the appropriate rate and time. This ensures that NICE manages public monies appropriately, acts in line with financial regulations and aligns with published and monitored start dates for the evaluation process for each topic.
2. Where an evaluation has required substantially different resources of a standard assessment, alternative refund models may be explored by NICE using a methodology consistent with [HM Treasury’s guidance, Managing Public Money (MPM)](https://www.gov.uk/government/publications/managing-public-money).
3. All refunds are subject to a standard administration charge. The administration charge allows NICE to recover the administrative costs related to staff and [NHS Shared Business Services](https://www.sbs.nhs.uk/) used to raise and complete the refund. The administration charge is £100 per refund and £25 for small companies eligible for the discount.