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

NICE response to consultation

# Executive summary

1. In November 2023, NICE conducted a consultation on the processes and procedures of cost recovery for the Technology Appraisals (TA) and Highly Specialised Technologies (HST) work programme.
2. The review was carried out 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), where 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.
3. 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 2023-24 review considered the structure, mechanism, and application of charging.
4. In April 2024, NICE will be in year 5 of charging for the TA-HST work programme 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://assets.publishing.service.gov.uk/media/65c4a3773f634b001242c6b7/Managing_Public_Money_-_May_2023_2.pdf), and secure the programme's financial sustainability.
5. NICE understands that the fee increase may contribute to making the UK a difficult environment for industry and potentially impacts the attractiveness of the UK as a launch market. Reluctantly we are unable to reduce the fees, but we have in response to comments received provided further reasoning for the increase.
6. In response to the feedback received to the consultation, the proposals have been revised as described in table 1. This document lays out the NICE response to support transparency of the cost recovery processes.

Table 1 – summary of proposals and updated procedures

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Proposal title | Draft detail –consultation paper | Final detail – updated procedures |
| 1 | Confirming evaluation timelines and commitment to pay | Request for Unique Reference Number (URN) 19 months before guidance publication - approximately 12 months before Invitation to Participate (ITP). | Change to timeline of URN request – now 6 months before Invitation to Participate (ITP). |
| 2 | Introduction of a change fee | Change fee set at £18,610. | Change fee reduced to £9,305.  Clarity of when and how a change fee will be applied. |
| 3 | A charge for technical engagement | An additional charge for technical engagement. | This proposal will not be implemented - no charge will be applicable for technical engagement. |
| 4 | A charge for pilot topics and amendments to processes | Pilots and amendments to be subject to divergent fee. | Clarification of when and how a divergent fee will be applied and calculated. |
| 5 | Update to refund procedures | Refund not applicable post External Assessment Report. | The key milestones used for cost recovery and refunds are now public.  Clarification when a refund will be applicable based on the key milestones.  The administration fee has been removed. |

1. The changes described in this paper will come into effect on 1 April 2024.
2. Following this review, NICE will move to a dynamic approach to updating our cost recovery procedures. We will review the procedures in line with the regular business planning cycle and have listed areas for future consideration at the end of this document.

## Introduction

1. In November 2023, NICE conducted a consultation on the processes and procedures of cost recovery for the TA-HST work programme.
2. A stakeholder engagement event took place on 2 November 2023, where life science industry organisations and representatives were provided with an early view of the proposals and invited to ask questions of the panel. 247 people registered and 176 people attended the event.
3. A total of 27 stakeholders, including pharmaceutical organisations and industry bodies provided comments to the consultation.

## The cost recovery consultation

1. The consultation presented 5 main proposals:
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
7. Stakeholders were asked to provide feedback on the proposals as laid out in the [consultation paper](https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/consultations/TA-HST-charging-review-23-24-consultation-paper.docx). For all proposals stakeholders were asked
8. Does the paper clearly explain the justification for the proposal?
9. Does the paper provide enough detail on the proposed changes?
10. What consequences of implementing the proposed changes are there for industry?
11. Do you have any other feedback to share on the proposal?
12. In response to the review, the charging procedures have been updated and replace any information previously published on the NICE website.

# Findings from the consultation, NICE response, and next steps

## Fees for 2024-25

1. NICE did not specifically ask for comments on the new fees, but received comments referencing the fees and the background that was provided in the [consultation paper](https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/consultations/TA-HST-charging-review-23-24-consultation-paper.docx).

### Summary of comments

1. Comments on the increased 24-25 fees were heard throughout all the proposals. The comments focussed on the following key themes:
   1. A 23% increase to fees is too high.
   2. Transparency and granularity of the resourcing requirements for evaluations, and how this has been calculated and applied is missing.
   3. Some costs have been built in for stages which may not feature in every evaluation (e.g. second committee meetings ACM2).
   4. Industry should not support NICE internal research and development and improvement functions.
   5. A view that NICE is not acting within the realms of [HM Treasury’s guidance, Managing Public Money (MPM)](https://assets.publishing.service.gov.uk/media/65c4a3773f634b001242c6b7/Managing_Public_Money_-_May_2023_2.pdf).

### Our response

1. When setting the fees, NICE followed the principles set out in [HM Treasury’s guidance, Managing Public Money (MPM)](https://assets.publishing.service.gov.uk/media/65c4a3773f634b001242c6b7/Managing_Public_Money_-_May_2023_2.pdf) (Chapter 6) and will continue to follow these when reviewing fees in the future. The basic principles followed are listed below:
   1. The charge was set to recover full costs (direct costs, indirect costs, and overheads).
   2. The charge was set to neither profit at the expense of consumers, nor make a loss for taxpayers to subsidise.
   3. Control costs as if the costs were funded by the taxpayer.
   4. Will normally require and rely on legislation by ministers (in our case Statutory Instrument 2018 No: 1322).
2. The charge does not include any costs that are funded via the [2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth](https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth). As outlined above, the only costs included are:
   1. Direct costs - directly incurred and controlled by the TA-HST team.
   2. Indirect costs - incurred by support teams essential to guidance delivery.
   3. Overheads - a proportion of back office and estates costs allocated to TA-HST activity.
3. 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 2 – changes to direct, indirect fees and overheads

|  |  |  |
| --- | --- | --- |
| 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. 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, 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. 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. Included in fees for the first time:
      1. Medicines Optimisation Team – to support cost comparison activity, and standard appraisals.
      2. [Science Policy and Research Team](https://www.nice.org.uk/about/what-we-do/our-research-work) – supporting the delivery of modular updates and broader research and methods related to TA-HST activity only.
2. When reviewing the fees, NICE must also consider the capacity of the work programme. The projected total for 2024-25 is 80 units of work, based on a combination of previous year’s actual activity, 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.
3. 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.
4. NICE continues to subsidise a significant amount of the TA-HST programme (see table 3) and continues to do so in 23-24 and 24-25. We need to close the gap to comply with [HM Treasury’s guidance, Managing Public Money (MPM)](https://assets.publishing.service.gov.uk/media/65c4a3773f634b001242c6b7/Managing_Public_Money_-_May_2023_2.pdf), and secure the financial sustainability of the programme. Therefore, the fees will rise as outlined in the original consultation document.

Table 3 – TA-HST financial performance 2019-20 to 2022-23

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Financial year | Full cost £'m | Income £'m | Deficit £'m | Deficit % |
| 2019-20 | 9.5 | 3.6 | 5.9 | 62% |
| 2020-21 | 10.7 | 7.0 | 3.7 | 35% |
| 2021-22 | 11.5 | 8.6 | 2.9 | 25% |
| 2022-23 | 12.6 | 10.2 | 2.4 | 19% |

1. TA-HST guidance development relies on structured processes and timelines that are predictable and robust; this requires a structured clear charging framework without bespoke pricing. During the evaluation process, both NICE and companies can expect to receive a standard and quality of service. To monitor and address this level of quality, in 2024-25, NICE will look to implement an ‘after action review’ to take place after guidance publication. This will provide an opportunity for a two-way feedback loop between NICE and the company. Our aim is to implement this for topics with an Invitation to Participate (ITP) from 1 April 2024 onwards.

## Proposal 1 – confirming evaluation timelines and the commitment to pay

1. To assist NICE in recovering lost opportunity costs, reduce the impact of topic rescheduling, we proposed expediting topic scheduling and requesting Unique Reference Number (URN) to 19 months before guidance publication. The proposal explained that the URN must be received for the timeline to be confirmed in the NICE work programme.

### Summary of comments

1. Most respondents disagreed with this proposal. Feedback highlighted that it is too early to request the URN 19 months before guidance publication. We heard that:

* There is significant regulatory uncertainty
* It is unrealistic to expect timelines to remain fixed and that NICE should be able to manage this flexibility
* Budgets for health technology assessment may not be agreed
* Having the URN run over multiple fiscal years can cause challenges
* Pivotal trial data is unlikely to be available
* Companies may not have made a launch decision

1. However, we also received comments noting that greater predictability and efficient resource allocation is important to industry, and earlier scheduling is welcomed.
2. Stakeholders commented that cost recovery should be aligned with key milestones, linked to the stages of the evaluation, rather than a one-off and upfront payment.
3. There was also disagreement with the use of ‘company driven changes’ terminology.

### Our response

1. Considering the comments received we will be modifying our approach to move forward with the implementation of this proposal. The URN will now be requested approximately 6 calendar months before the ITP issue date and cost recovery initiated at the optimum time for NICE and the company.
2. If the proposal was implemented as written in the consultation, the URN would have been required 19 months before guidance publication; this is approximately 12 months before ITP issue date. We acknowledge that this is too early for companies to manage and for NICE to operationalise. Guidance publication was assumed at month 0, however cost recovery starts with the ITP and the timeline for charging has been updated to reflect this.
3. The URN must be received before the scope consultation can begin. The URN signals a company’s commitment to the scheduled timelines for the evaluation of its technology.
4. NICE reserves the right not to start the evaluation until payment is received. If payment is delayed, the original agreed timeline may be at risk.
5. We acknowledge that regulatory timelines can be unpredictable and NICE will continue to engage with companies to minimise the impact of regulatory updates on the TA-HST work programme. NICE will continue to drive forward with process improvements that support a more predictable work programme to better inform financial forecasting, reporting, and resourcing.
6. Industry requested NICE to consider the evaluation payment schedule and invoicing process and align this to the key milestones. There are currently operational limitations to moving to this approach, which would require further funding through the cost recovery fees. However, NICE commits to further reviewing this in 2024-25.
7. We have engaged further with Industry to better understand the challenges faced by companies during the MHRA regulatory process. We recognise that there are also factors outside of a company’s control, and NICE will continue to utilise and embed the most appropriate mechanisms to access regulatory information e.g. [UK Pharmascan](https://www.ukpharmascan.org.uk/), [MHRA Operational Information Sharing](https://www.gov.uk/government/publications/operational-information-sharing/operational-information-sharing-guidance) and regular pipeline meetings with companies.

## Proposal 2 – introduction of a change fee

1. To address the impact of topic rescheduling and to recover lost opportunity costs, we proposed implementing a change fee. The proposal explained how a change fee of £18,610 would apply if NICE received a request to change the timelines, after they were confirmed with the company.

### Summary of comments

1. Feedback highlighted a significant risk and objection to the proposal, and industry behaviours may move towards giving conservative timelines or be discouraged from committing to evaluation timelines. We heard that the introduction of the change fee combined with an early request for the URN (Proposal 1 – confirming evaluation timelines and the commitment to pay) would create a greater risk of a change fee being incurred.
2. Industry noted that it would be unfair to penalise companies for regulatory changes that are out of their control and NICE must be able to operate in an uncertain regulatory environment.
3. We heard that it was unclear when the change fee would apply and in what specific scenarios it would be enforced.
4. Some stakeholders explained that the introduction of the change fee combined with the increased fees for 2024-25 could have negative impacts on budgets and forecasting and may push launching a medicine in the UK at risk. It was suggested that a sliding scale of fees would be more appropriate than a single flat fee applied to timeline changes.

### Our response

1. Considering the comments received we will be modifying our approach to move forward with the implementation of this proposal. NICE agrees with comments that the combination of Proposal 1 – confirming evaluation timelines and the commitment to pay and Proposal 2 – introduction of a change fee, as written in the consultation would be difficult to implement; Proposal 1 – confirming evaluation timelines and the commitment to pay has been amended.
2. We have considered a proportionate change fee, based on the specifics of the delay for each topic. In some cases, a proportionate change fee would be much higher than the proposed figure of 10%.
3. NICE recognises predictability is important to industry and a smaller flat fee of 5% of the standard Single Technology Appraisal (STA) fee will be implemented. The fee recovers topic selection, scoping and scheduling resources and mitigates lost opportunity costs for allocated resources including NICE staff, external assessment groups, and committee slots. Key milestones and the linked percentage of guidance evaluation can be viewed in Proposal 5 – updates to refund procedures.
4. The change fee will apply if a request to amend the timeline is received in the four calendar months prior to the ITP date. A change fee can be applied to an evaluation more than once. See Appendix 1 – TA-HST cost recovery change fee process.
5. A change fee will **not** apply if:

* An ITP has been issued. In this case, the refund process will be followed (if applicable). See Proposal 5 – updates to refund procedures
* The company is engaged in a Multiple Technology Appraisal (MTA)
* NICE initiates the change to timelines

1. We acknowledge that companies cannot always predict or control the impact of regulatory changes on licencing timelines and NICE guidance publication. NICE will continue to engage with companies to minimise the impact of regulatory updates on the TA-HST work programme.
2. As explained in the consultation paper, company requests for scheduling changes accounted for 37% of changes to the work programme between April and October 2023. The high volume of requests for change has a significant impact on the ability to support a predictable work programme. The implementation of a change fee supports partnership working, whereby NICE and companies cooperate and work together to schedule evaluations at the optimum point for evidence submission.

## 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.

### Summary of comments

1. We received some agreement with the proposal, but most respondents had concerns.
2. Industry felt that the charge itself was high and contradictory. It was identified that NICE may recoup extra costs for a process which if initiated, should speed up the evaluation process. A successful technical engagement should result in an evaluation proceeding straight to final draft guidance after one committee meeting, removing any requirement for a second committee meeting to be held. If technical engagement is added, it is in fact cost saving and industry felt in those cases, charges should be reduced.
3. We heard that if the proposal was implemented, and industry were expected to pay, the company should also be able to request and ask for technical engagement to be included in an evaluation.
4. Some felt that a 5% charge was too high, and acknowledged that expert input had recently been removed, meaning there is now less engagement. It was noted that the unpredictability of inclusion of technical engagement creates uncertainty for budget planning and could therefore be a negative financial impact on treatments with uncertain evidence bases (e.g. rare diseases).

### Our response

1. Considering the comments received, NICE has decided not to implement this proposal at this time.
2. As of 1 January 2024, two evaluations in the work programme have had technical engagement included. NICE will continue to monitor the number of evaluations with technical engagement and impact on cost recovery of the work programme.
3. NICE agrees that if used appropriately by NICE and the company, technical engagement can result in the evaluation proceeding to final draft guidance after the first committee meeting.
4. The approach to technical engagement has been updated in the [Health technology evaluations: interim methods and process guide for the proportionate approach to technology appraisal](https://www.nice.org.uk/process/pmg40/chapter/introduction) and the initiation of technical engagement remains a NICE decision. Companies cannot submit a request for technical engagement to be included in the evaluation process.

## 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 a 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 divergent 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)

### Summary of comments

1. We received feedback that the consultation document provided minimal information on the proposal, it lacked justification and detail. Industry felt that the fees could disincentivise participation and collaboration in pilots. It was also noted that companies should not be subsidising research and development through cost recovery.
2. We heard that industry assume a level of risk when agreeing to be involved in piloting processes and methods for an evaluation; this should be reflected in the fee, and the fee should be lower because of this.
3. We heard that the statement “we expect the fee to be no more than the largest or lowest fee set out within the NICE charging procedures” is unhelpful and creates uncertainty for budget planning.

### Our response

1. We have carefully considered the responses received and confirm that a divergent fee will apply to evaluations where standard processes have been amended.
2. It is appropriate to apply divergent fees to accurately reflect the resource and unit capacity utilised by an evaluation. These fees have been previously referred to as ‘exceptional charges’ within the charging procedures.
3. Cost recovery will be based on the standard fees and the key milestone weightings. NICE will explore a fee based on the evaluation direct resource effort, relevant indirect costs and overheads using a methodology consistent with [HM Treasury’s guidance, Managing Public Money (MPM)](https://www.gov.uk/government/publications/managing-public-money). In exceptional cases, it may be necessary to deviate from the standard fees to reflect the unit capacity utilised. It is not expected that any fees will exceed the maximum fee in the fee table.
4. Piloting and testing innovative approaches will not always cost less; there is no defined process, and additional or fewer NICE resources may be used. NICE tracks internal timesheet data of the TA-HST programme, and the insights derived will help inform future cost recovery models.
5. Previously, NICE has applied similar methods of cost recovery to pilot evaluations. Once of the [NICE Principles](https://www.nice.org.uk/about/who-we-are/our-principles) is to “Describe our approach in process and methods manuals, and review them regularly” and this approach will be included in the updated procedures.

## Proposal 5 – updates to refund procedures

1. To give industry clarity on refunds, the consultation paper explained that there is no eligibility for a refund once a company has submitted to NICE and the submission review has started by the Evidence Assessment Group. We advised that NICE would issue a refund for topics that are rescheduled 4 months after the ITP has been issued, and when an STA follows the streamlined committee decision process, a refund matching the cost comparison fee would apply. We proposed to retain the administration charge for all refunds.

### Summary of comments

1. Feedback from industry signalled a request for more transparency on refund calculations, specifically the refund amount applicable at each milestone and explanation as to why a refund is not applicable after the Evidence Assessment Report (EAR) has been received.
2. We heard that the administrative charge is unjustified and inconsequential when considering the overall uplift in fees.
3. Industry would like NICE to reconsider the evaluation payment schedule, signalling a preference for a phased payment model over a refund process. We heard that the refund procedure creates uncertainty for budget setting and financial planning, and that companies should not be owed money by statutory organisations.
4. Some also stated it is unclear exactly “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://assets.publishing.service.gov.uk/media/65c4a3773f634b001242c6b7/Managing_Public_Money_-_May_2023_2.pdf),” means.

### Our response

1. We have carefully considered the responses received, and Appendix 2 - TA-HST cost recovery updated wording for refund procedures has been updated.
2. TA-HST processes have become extended and complicated over time, in part due to industry request for flexibility. Whilst cost recovery is initiated at the optimum time for NICE and the company, there may be scenarios where a refund is necessary.
3. 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. The key milestones are used as a baseline for refund calculations, as described in table 4. The exact refund owed may differ if additional resources and overheads are utilised.

Table 4 – TA-HST cost recovery percentage effort at key milestones

|  |  |
| --- | --- |
| Key milestones | Weighting (%) |
| ITP\* | 18% |
| Evidence Submission | 7% |
| Evidence Assessment Report (EAR) deadline | 7% |
| Committee preparation stage 1 | 12% |
| Committee meeting 1  (includes post meeting activities and Draft Evaluation Document) | 21% |
| Committee preparation stage 2 | 8% |
| Committee meeting 2  (includes post meeting activities and Final Evaluation Document) | 17% |
| Guidance Publication | 10% |

\*includes pre ITP resource such as topic selection, scoping and scheduling

1. Refunds are not applicable when an evaluation has started or passed the committee preparation stage for the first committee meeting. This reflects the utilisation of resources such as NICE staff, external assessment groups and committee slots which cannot be reallocated.
2. A refund remains applicable if the evaluation cannot be completed after it has started, in the case that the technology does not receive regulatory approval. NICE will refund the amount paid less any costs incurred during the evaluation dependent on the milestone stage, including when it has started or passed the committee preparation stage for the first committee meeting.
3. If on completion of an evaluation NICE recognises that it has not used all resources included in the full fee amount, we will initiate discussions with the company and consider if a refund is appropriate.
4. The standard administration charge has been removed from the procedures and will not apply to refunds processed after 1 April 2024.
5. As explained previously, there are currently operational limitations to changing the approach to the evaluation payment schedule, which would require further funding through cost recovery. However, NICE commits to reviewing this in 2024-25.

## Future considerations

1. The following areas will be considered via a future dynamic approach to updating cost recovery, as part of the regular business planning cycle.

* The impact of the rate of committee members that will receive renumeration in 2024-25.
* 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.
* A review of the small company criteria and discount.
* A review of the evaluation payment schedule and invoicing process, to see this aligned with the key milestones
* A review of the fee structure for simple and complex Multiple Technology Appraisals (MTA)
* The insights from TA-HST programme internal timesheet data, to inform future cost recovery models.
* The impact of process improvements supporting a more predictable work programme, informing financial forecasting, reporting, and resourcing. For example improved data collection.

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# Appendix 1 – TA-HST cost recovery change fee process



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# Appendix 2 – TA-HST cost recovery 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 fee. 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. There are amendments to process, or divergent fees are applied.
   4. The technology does not receive regulatory approval and the evaluation cannot be completed after it has started. NICE will refund the amount paid less any costs incurred during the evaluation dependent on the milestone stage and will apply if the preparation stage for the first committee meeting (committee preparation stage 1) has started or passed.
   5. If the ITP has been issued and the timelines for the evaluation are rescheduled for over 4 months later, then NICE will provide a proportionate refund considering the milestones met. We will restart the charging process in line with the new ITP date and charge the applicable fee. 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.