NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Accreditation process manual - renewals

Process manual for renewing accreditation for producers of guidance, advice and recommendations for practice already NICE accredited

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Accreditation Renewal Process Manual

1 Introduction

NICE no longer accepts and processes new applications for NICE Accreditation. NICE is keen to continue to have an ongoing relationship with accredited guidance producers and will still encourage producers to maintain and ideally continue to improve their processes via this new renewal process.

2 Aims, scope and approach

2.1 Aims and scope

2.1.1 The purpose of NICE **accreditation** is to help users identify the most trusted sources of guidance that have been developed using critically evaluated high-quality processes. In the long term, this will improve the quality of information produced for health and social care decision-makers. The accreditation programme assesses the processes by which guidance is developed and not the content. Individual pieces of guidance produced via an accredited process bear the **Accreditation Mark**.

2.1.2 New applications are no longer accepted, but NICE now has a renewal process to ensure that existing accredited producers maintain the standards of accreditation. Their process and guidance examples will continue to be reviewed every 5 years.

2.2 Criteria used in accreditation

2.2.1 The **accreditation criteria** are based on the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument. The AGREE instrument was developed to assess the quality of individual clinical guidelines, and has been expanded to encompass other types of guidance that fit the definition for NICE accreditation. The assessment criteria may be applied according to the focus of the guidance product under consideration. This allows for a complete assessment on a case-by-case basis. Please see appendix A for further details.

2.3 Term of accreditation

2.3.1 The term of Accreditation lasts for 5 years from the date of the last accreditation decision (new or renewal).

2.4 Equality statement

2.4.1 The Accreditation programme operates in accordance with the NICE equality scheme (available from **NICE equality objectives and equality programme**). Equality considerations are taken into account at each stage of the renewal process. Any equality issues raised are recorded in the equality impact assessment (in accordance with the documented equality impact assessment procedure).

3 Overview of the accreditation renewal process

3.1 Summary of key stages in the process

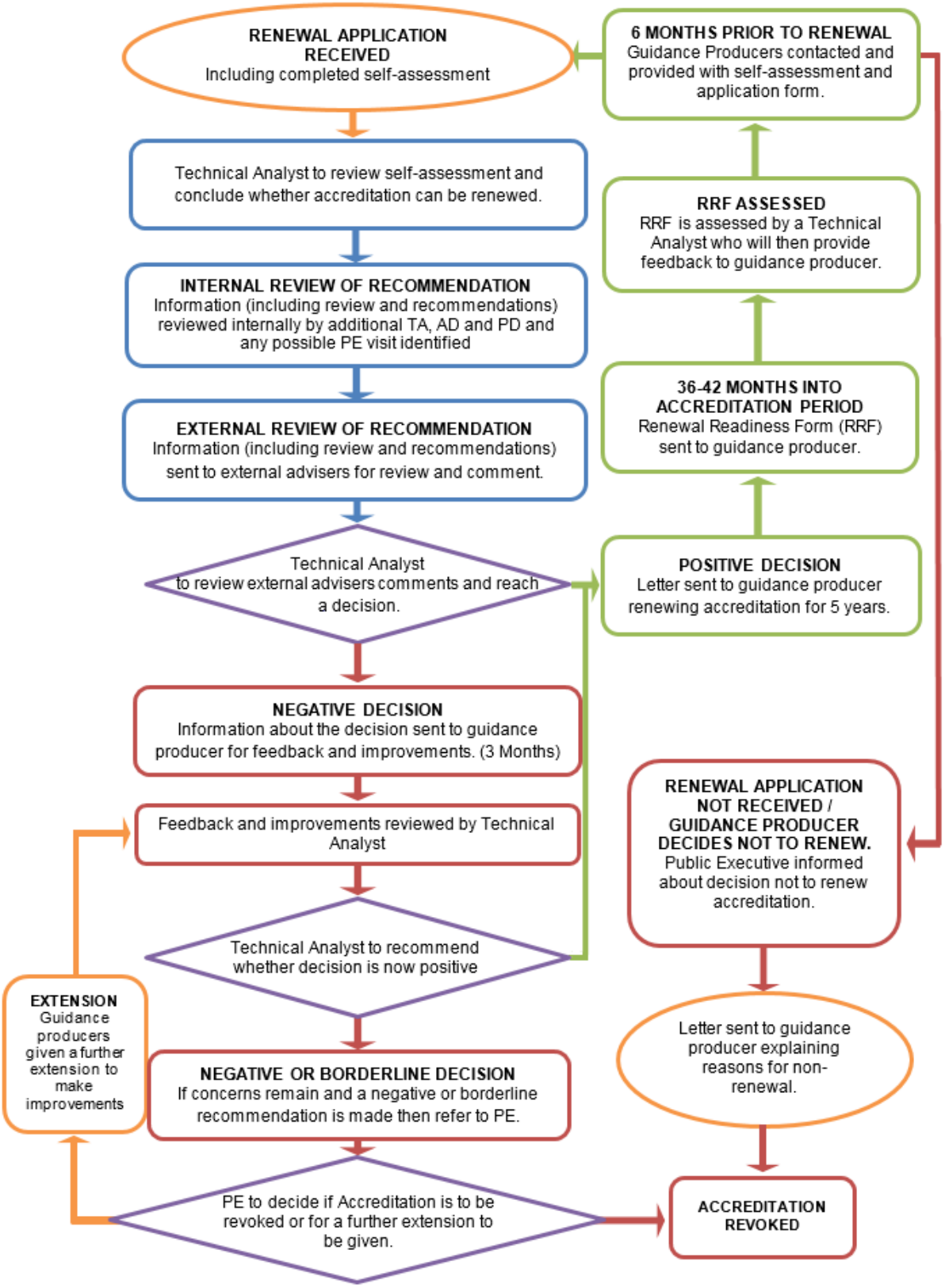
3.1.1 Figure 1 summarises the key stages in the accreditation renewal process. Further detail on each of the steps in the accreditation renewal process is provided in sections 3.2 to 3.14.

3.1.2 For transparency, accredited guidance producers terms are published on the NICE accreditation website.

3.2 Pre-renewal application support and advice

To help NICE accredited guidance producers assess their readiness for accreditation renewal and understand how to apply, NICE will maintain contact and discuss the process with a producer during their 5 year term. Information, tools and materials are available under accreditation renewal section on the NICE website.

Figure 1 Flowchart summarising the accreditation process



3.3 3 years into an accreditation term

3.3.1 During the term NICE will make reasonable efforts to contact the guidance producer. It is incumbent on the guidance producer to ensure that NICE has an up to date point of contact to liaise with.

3.3.2 Between 36 and 42 months into their term an accredited guidance producer is provided with a renewal readiness form (RRF). By completing this, it enables the producer to assess their readiness for renewal. Details of what is required for completion are included within the form.

3.3.3 The RRF covers the current process used by the producer and recent examples of implementation. The producer should update the RRF with details of any changes to their process. The producer will also be asked to comment on progress for any recommendations made at the accreditation decision, if they remain relevant, and alignment with current standards.

3.3.4 The guidance producer is encouraged to complete the RRF within 3 months of receipt for it to be most beneficial to maintaining accreditation.

3.3.5 Individual guideline applications do not need to be renewed and so do not need to complete a renewal readiness form.

3.3.6 A guidance producer accredited before March 2015 will need to show that they meet the requirements of the updated accreditation process introduced from December 2014. These differences can be identified and discussed at the assessment. Completion of the RRF will enable identification of any shortcomings and provide the maximum opportunity for the guidance producer to address any concerns.

3.4 Producing the renewal readiness assessment response

3.4.1 The RRF and any other information provided by the guidance producer is assessed and validated against the accreditation criteria by a technical

analyst. The analyst briefly summarises whether the guidance producer's processes for guidance development still meet the assessment criteria, identifies any areas of weakness and any changes that may need to be discussed.

3.4.2 The analyst feeds back to the producer details of any criteria that may need some actions to show improvement. The focus will be on what is required to maintain accreditation. Timescales for renewing at the 5 year point will also be explored, to agree when the renewal will be submitted. This will enable planned changes such as a process manual review and guidance examples not available in that timescale to be accommodated.

3.5 Categorisation of follow up to renewal

3.5.1 After the conversation with the guidance producer and any update of the assessment has been made, the analyst will categorise the producer as follows:

- The producer has a good process and examples and is on course to maintain achievement of relevant criteria at renewal. Maintain minimal contact.
- The producer has some actions to implement to ensure successful renewal. Maintain contact, supporting and advising on possible developments.

3.6 Nearing the end of term of accreditation

3.6.1 The guidance producer will be contacted by NICE 6 months before the end of the 5-year accreditation period to formally notify them of the upcoming expiry of their accreditation term. The guidance producer will be asked to confirm if they intend to apply for accreditation renewal. The accreditation renewal self-assessment may be submitted up to 6 months before the accreditation term expires.

3.6.2 If the guidance producer confirms that they will not apply for accreditation renewal at the end of the term, the guidance producer will be expected to stop using the Accreditation Mark at the appropriate expiry date in line with the agreed accreditation terms and conditions. Existing guidelines already carrying the Accreditation Mark will remain accredited as they were produced to an accredited process. Any guidelines produced to this process after the expiry date will not carry the Accreditation Mark.

3.6.3 The accredited guidance producer is provided with a self-assessment renewal table (SART) to complete. Details of what is required for completion are included within the assessment. Guidance producers are requested to also provide their documented policy or process for the production of guidance and some examples of guidance which provide evidence that the process has been used to develop them.

3.6.4 The guidance producer should submit their SART before their term expires, unless an alternative date has been agreed. At NICE's discretion, a guidance producer's term may be extended by a maximum period of three months if required to complete the SART and associated documentation in order to apply for renewal. Extensions will be considered on a case by case basis.

3.6.5 If the guidance producer does not submit a renewal application or does so later than the end of the month in which their term expires despite

engagement, the producer will be deemed to have terminated their accreditation status and will no longer be able to use the accreditation mark in future. This is outlined in the signed terms and conditions they have agreed to work with.

3.7 Producing the renewal application response

3.7.1 The SART and any other information provided by the guidance producer is assessed and validated against the accreditation criteria by a technical analyst. The analyst summarises whether the guidance producer's process for guidance development still meets the assessment criteria. Where there are queries, these will be explained.

3.7.2 Having completed the assessment the analyst will have concluded

- That the producer is maintaining a robust development process and that accreditation can be renewed or
- That there are concerns suggesting the producer is not maintaining the level of accreditation set.

3.7.3 The assessment is then checked by the Associate Director or Programme Director, System Engagement and they identify whether the application may need to be considered by Publication Executive (PE), so that it can be scheduled.

3.8 External peer review

3.8.1 In order to provide an independent and reliable review of the recommendation, the assessments are seen by at least 2 external advisers. At least one of these will provide a lay perspective.

3.8.2 External advisers are selected to review an application based on their expertise and experience. Typically, external advisers have up to 10 working days to peer review the assessment produced by the analyst.

They advise whether they agree or disagree with the criteria assessments and the recommendation and why.

3.9 If the producer is maintaining a robust process

3.9.1 If the producer is identified as easily maintaining an accreditable process a letter confirming this is sent to the producer. The guidance producer is invited to re-sign the necessary **terms and conditions** (provided separately). This document includes a statement about ensuring the same process will continue to be used to produce guidance, and that any deviation from this process will be notified to the accreditation team.

3.9.2 The renewal date is amended on the accreditation pages of the NICE website, and the guidance producer can continue to use the Accreditation Mark.

3.9.3 If the producer is identified as just maintaining an accreditable process and the recommendation is considered to be borderline the reports will be updated and discussed at PE. Improvements may be identified and recommended and a period to begin making them may be given before the final decision is made.

3.10 If the producer is not maintaining a robust process

3.10.1 If after external review concerns remain that the guidance producer is not maintaining the level of accreditation set they will be given a period of 3 months to make improvements, otherwise accreditation may be revoked. After 3 months further assessment will identify whether improvements have been made or are in hand. The reports will be updated and discussed at PE.

3.10.2 If the decision is to discontinue accreditation for the producer they will be sent the report and have 20 working days from the date the report is sent to challenge the decision. See section 3.11. If accreditation has been discontinued, the guidance producer must stop using the Accreditation

Mark. Content developed by guidance producers no longer accredited continues to be available through NICE Evidence, where applicable (non-accreditation does not result in a producer's content being removed from NICE Evidence).

3.10.3 If the decision is to renew accreditation the producer is notified as in 3.9.

3.10.4 The status of the guidance producer is amended on the accreditation pages of the NICE website.

3.11 Resolving any challenges to the decision

3.11.1 The **resolution process** is a final quality assurance step, intended to ensure that the accreditation process is fair and that accreditation decision-making has not unreasonably deviated from the process described in this document.

3.11.2 Only resolution requests made on the grounds that there has been a 'breach of process' will be considered. Guidance producers have 20 working days from the date they are notified of the final accreditation decision to request resolution by email, fax or letter to the Associate Director managing accreditation. The guidance producer may also request a resolution at any point in the accreditation renewal process. The request should specify the breach of process and provide supporting information so that NICE can fully understand the nature of the concern and provide an appropriate remedy if there has been a breach of process. Consideration of a resolution request will only be made if the grounds for resolution are clearly identified and stated.

3.11.3 If a resolution request is received, publication of the accreditation decision is suspended pending an investigation of the request. If no request is received, the accreditation decision is published as soon as possible thereafter.

3.11.4 The Director of Health and Social Care will decide within 20 working days whether the request falls within the scope of the resolution process. If the Director of Health and Social Care considers that there has been no breach of process, or that the request does not have a reasonable prospect of success, the decision is relayed to the guidance producer and the accreditation decision proceeds to publication.

3.11.5 If the Director of Health and Social Care considers that there has been a breach of process, a meeting of the Resolution Panel is convened within 20 working days of the conclusion of the initial scrutiny process. The Resolution Panel consists of three NICE Board members (including a non-executive director and an executive director not previously involved in the accreditation decision). The Resolution Panel decides whether there has been a breach of process and, if so, what action is appropriate. It will be chaired by the Director of Health and Social Care. In the event of there being a resolution request that relates to NICE guidance, an independent panel will be convened.

3.11.6 The Resolution Panel will find either that there has been no breach of process and that the final accreditation decision can be published as proposed, or that there has been a breach of process. If there has been a breach of process, the Resolution Panel decides what action is appropriate to remedy the breach. This is likely to mean repeating the accreditation renewal process from a certain step.

3.11.7 The decision reached by the Resolution Panel is final.

3.12 Producers whose term expires before March 2019

3.12.1 For producers whose term expires before March 2019 the accreditation team will not be able to implement this process in full. Although contact at 36 months should have taken place, the form of that will have been

different from the intended renewal process. Contact at 48 months may also have been made to formally notify the date of expiry to term.

3.12.2 For those producers within a year of their expiry date a conversation will be arranged to talk through the questions that would in future be asked around 36 months into their term. This will identify whether producers are maintaining a good process or not. For those who are, continue as per this process ensuring that the guidance producer has been formally notified of the expiry date of their term. For those who may need to make improvements, NICE will identify actions needed to ensure that renewal can be achieved, maintaining regular contact and support.

3.12.3 It should be noted that all of these guidance producers achieved their accreditation to the previous process and may therefore need to make improvements to meet the current process criteria.

3.13 Interim contact

3.13.1 Contact between relevant member(s) of the accreditation team and the guidance producer, will take place 36 months after accreditation is awarded or renewed, see section 3.2. Depending on the outcome of the assessment of readiness to renew, regular contact may occur after this.

3.13.2 Guidance producers are also encouraged to contact the accreditation team at any time if they need any support or advice on process changes.

3.14 Notifying process changes

3.14.1 Throughout the accreditation period, an accredited guidance producer should contact NICE in order to update on any changes to accredited guideline production processes. They should do so by emailing **Accreditation@nice.org.uk** outlining the key aspects of any change to existing accredited processes.

3.14.2 A member of the team will review this update and consider any implications for current accreditation status to ensure there is no lowering of standards and respond to the producer as appropriate. It may be that these changes are reflected in the RRF which forms the basis of the 3 year meeting outlined in section 3.3. If the changes are considered to be significant, an earlier meeting between NICE and the producer may be suggested.

4 Who is involved in the accreditation renewal process?

Table 1 Key participants in the accreditation renewal process

Guidance producer	The guidance producer is the accreditation applicant. Guidance producers prepare 'systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing.' The key roles of the guidance producer include: • contributing to a discussion with the accreditation team around 3 years into their term • completing the RRF • providing the information necessary to perform the accreditation self-assessment (SART and supporting documentation) if they wish to continue accreditation status • complying with the Terms and Conditions.
System Engagement team	The accreditation programme is managed by the System Engagement programme and is accountable to the Director of Health and Social Care. Key roles of the programme include: • engagement with guidance producers before,

	during and after the accreditation renewal process • reviewing and validating the information provided by guidance producers and requesting additional information if necessary • preparing a report based on the guidance producer's submission, which provides an analysis of compliance with the criteria • notifying the guidance producer of the final decision.
External advisers	The external advisers are individuals who have expertise and experience in guidance development. They may also have expertise in a specific subject or topic area. Some advisers will have a lay perspective and at least 1 person from this background should be included in a review. They review the report and application and provide an independent opinion particularly when the recommendation is not to renew.
NICE Publication Executive	The NICE Publication Executive is an executive committee that acts under delegated authority of the NICE board to review and approve documents for publication and ensure the accreditation process has been followed. The key role of the NICE Publication Executive is to review and approve any borderline decisions and consider any decisions to revoke accreditation status.

Appendix A: Criteria for the accreditation programme

The accreditation criteria provide a framework for assessment by the accreditation team of the quality and rigour of the process used by guidance producers to develop guidance. These criteria are based on the AGREE Instrument[1]. The criteria focus on the process used for developing guidance rather than the content of individual guidance or products.

There are 25 key assessment criteria, organised in 6 domains. Each domain is intended to capture a separate dimension of the quality of the process used to develop guidance. Table 2 describes each of the 6 accreditation domains and their associated assessment criteria. Guidance producers are assessed to review the extent to which their process for developing guidance meets these criteria. In addition, the accreditation technical analysts evaluate an arbitrarily selected sample of guidance to ensure that the guidance producer's processes are implemented consistently.

The accreditation criteria are based on the AGREE Instrument, which was developed to assess the quality of clinical or practice guidelines. The NICE accreditation team has adapted the instrument to cover a wider range of guidance, and to focus on development processes. Please note that this is a guide only and each application is considered on its own merits according to the type of guidance, audience and organisation.

[1] The AGREE Collaboration. Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al for the AGREE Next Steps Consortium (2010) AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Canadian Medical Association Journal*

Table 2 Accreditation domains and criteria

Domain	Criteria
1. Scope and purpose is concerned with the overall aim of the guidance, the specific health questions and the target population.	These criteria consider whether the guidance producer has a policy in place and adhered to that requires them to explicitly detail: 1.1 The overall objective of the guidance 1.2 The clinical, healthcare or social questions covered by the guidance 1.3 The population and/or target audience to whom the guidance applies 1.4 That the producer ensures guidance includes clear recommendations in reference to specific clinical, healthcare or social circumstances
2. Stakeholder involvement focuses on the extent to which the guidance represents the views of its intended users and those affected by the guidance (patients and service users).	These criteria consider whether the guidance producer has a policy in place and adhered to that means it includes: 2.1 Individuals from all relevant stakeholder groups including patients' groups in developing guidance 2.2 Patient and service user representatives and seeks patients' views and preferences in developing guidance 2.3 Representative intended users in developing guidance
3. Rigour of development relates to the process used to gather and synthesise information and the methods used to formulate recommendations and update them.	These criteria consider whether the guidance producer has a clear policy in place and adhered to that: 3.1 Requires the guidance producer to use systematic methods to search for evidence and provide details of the search strategy 3.2 Requires the guidance producer to state the criteria and reasons for inclusion or exclusion of evidence identified by the evidence review 3.3 Describes the strengths and limitations of the body of evidence and acknowledges any areas of uncertainty 3.4 Describes the method used to arrive at recommendations 3.5 Requires the guidance producer to consider the health benefits, side effects and risks in formulating recommendations 3.6 Describes the processes of external peer review 3.7 Describes the process of updating guidance and maintaining and improving guidance quality

Domain	Criteria
4. Clarity and presentation deals with the language and format of the guidance.	These criteria consider whether the guidance producer ensures that: 4.1 The recommendations are specific, unambiguous and clearly identifiable 4.2 The different options for management of the condition or options for intervention are clearly presented 4.3 The date of search, the date of publication or last update and the proposed date for review are clearly stated 4.4 The content and style of the guidance is suitable for the specified target audience; if the public, patients or service users are part of this audience, the language should be appropriate
5. Applicability deals with the likely organisational, behavioural and cost implications of applying the guidance.	These criteria consider whether the guidance producer routinely considers: 5.1 Publishing support tools to aid implementation of guidance 5.2 Discussion of potential organisational and financial barriers in applying its recommendations 5.3 Reviewing criteria for monitoring and/or audit purposes within each product
6. Editorial independence is concerned with the independence of the recommendations, acknowledgement of possible conflicts of interest, the credibility of the guidance in general and their recommendations in particular.	These criteria consider whether the guidance producer: 6.1 Ensures editorial independence from the funding body 6.2 Is transparent about the funding mechanisms for its guidance 6.3 Records and states any potential conflicts of interest of individuals involved in developing the recommendations 6.4 Takes account of any potential for bias in the conclusions or recommendations of the guidance

Appendix B: Glossary

Accreditation

The process by which credibility, authority and competence are certified, and processes used by a producer of guidance are recognised by NICE as meeting the accreditation criteria.

Accreditation criteria

The criteria developed by the accreditation team that guidance producers must meet if they are to be accredited. The particular set of criteria that must be met depends on the type of evidence that the guidance producer develops. Different criteria apply to different types of evidence.

Accreditation Mark

The graphic that can be displayed by guidance producers on guidance produced via the accredited process in accordance with the terms and conditions.

Guidance

Systematically developed statements to guide decisions about appropriate health and social care to improve individual and population health and wellbeing.

Guidance producer

An organisation (or organisations in the case of jointly produced processes and guidance) that owns the process used to produce guidance and recommendations for practice.

NICE Publication Executive

An executive committee that acts under delegated authority of the NICE board to review and approve documents for publication and ensure the accreditation process has been followed.

Readiness to Renew Form (RRF)

Assessment by the producer of how they are meeting the accreditation criteria to enable identification of any improvements required.

Resolution Panel

Three NICE Board members (including a non-executive director and an executive director) who consider resolution requests on the grounds that there has been a breach of process.

Resolution process

The final quality assurance process undertaken if the guidance producer wishes to challenge the final accreditation decision. Publication of the accreditation decision is suspended pending the resolution investigation process.

Self assessment renewal table (SART)

Assessment by the producer of how they are meeting the accreditation criteria.

Stakeholder

An organisation with an interest in the accredited guidance producer. Stakeholders may include organisations representing health and social care professionals, NHS organisations, local authorities, national patient and carer organisations or manufacturers of drugs or equipment.

Terms and conditions

The terms and conditions of accreditation set out the rules that guidance producers must comply with when displaying the Accreditation Mark.