# National Institute for Health and Care Excellence
# Accreditation Process Manual Update for Consultation - Comments Proforma
**Consultation dates: 2 June to 26 August 2014.**

NB: Please do not amend the formatting of the form as these are collated electronically. If you are submitting comments on behalf of an organisation, please submit only one response per organisation.

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| **Name** | **Dr M. Firouz Mohd Mustapa** |
| **Role** | **Clinical Standards Manager** |
| **Organisation** | **British Association of Dermatologists** |
| **E-Mail Address** | **firouz@bad.org.uk** |
| **Consultation questions** | **Comments** |
| **Guidance producers answering questions at committee meetings**<br>1. What are the advantages and disadvantages to guidance producers attending committee meetings to answer questions on points of clarification? | Advantages:<br>• Facilitation of open discussion<br>• Expediency – any issues identified by the technical analysts and external reviewers could possibly be resolved there and then at the meeting<br><br>Disadvantages:<br>• The meeting may take up a bit more time<br>• Cost of travel<br>• Loss of work time |
| **Consultation on decisions to not accredit**<br>2. Apart from the guidance producer and independent external advisers should anyone else be able to comment on an accreditation recommendation? If so who and why? | Any national body producing guidelines may have a series of smaller affiliated groups who may wish to support the main body's accreditation application. For instance, the British Association of Dermatologists works very closely with a number of dermatology sub-specialty and patient support groups. Please see table below (Section 3.10 and 3.11). |
| **Cost effectiveness**<br>3. The assessment criteria currently do not cover cost effectiveness. How could the | Where appropriate, the British Association of Dermatologists factors in comparative costs for different treatment or interventional options, providing discussions on potential financial (and/or organisational) barriers to implementing recommendations, but would be grateful for some indication to what NICE means |

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| accreditation process take cost effectiveness into account to a) recognise and support the development of good processes in producers who already consider cost-effectiveness information, or implementation costs, when developing guidance and b) support others who do not? | | by, and expects of, “cost effectiveness”.<br><br>We are adopting GRADE and are aware that cost/resource allocation is a key factor in determining the strength of recommendations, but we have yet to reach this stage in any of our guideline projects.<br><br>Please note that we do not think a full-blown health economic analysis to be appropriate or affordable for many guideline producers. |
| **Conflicts of interest**<br>4. We recognise that the requirements for managing conflicts of interest as set out by the IOM are very challenging. What issues are raised by the proposed changes to the requirements for declaring interests and managing conflict? | | Please see the table below (Domain 6, page 56-57); in general, the new draft process manual should perhaps briefly list the different types of COIs (plus the ***specific/non-specific*** nature) in the different clauses on pages 56-57. It would also help if the terminologies used in the new draft process manual are aligned with those in NICE’s own COI policy document, the link for which would need to be updated as a result of the launch of the new NICE website. |
| **Accreditation renewal**<br>5. Should anything additional be taken into account when assessing processes for accreditation renewal and if so what? | | We are in the process of updating our guideline development manual in light of our adoption of GRADE in September 2013. We are therefore unable to reapply for accreditation at the point when our current term expires (May 2015) as two sample guidelines following our new process manual would have been required for submission together with the reapplication form, and this timeline in unrealistic. An extension to our accreditation term has been suggested, and one that we would be grateful for. |
| 6. Are there any other comments you wish to make? | | Please enter these comments in the table below |
| **Paragraph Number Primarily Related to your Comment (please enter only one)**<br><br>Indicate **‘general’** if your comment relates to the whole document | **Other Paragraph Numbers Related to your Comment** | **Comments**<br><br>**Please insert each new comment in a new row.**<br><br>**Please do not paste other tables into this table, as your comments could get lost – type directly into this table.** |
| Section 3.4.1 | | We acknowledge the requirement that accredited guidance producers must ensure that their process is fully adhered to in cases of collaborations with non-accredited guidance producers. |
| Section 3.8 | | The British Association of Dermatologists agrees with the proposal for guidance producers to be able to participate in the Accreditation Advisory Committee meetings. |

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| Section 3.10 and 3.11 | | We agree with the proposal to include an additional, independent peer-review step for recommendations not to accredit, on top of the public consultation. |
| Section 3.16 | | We agree with the proposal to move the interim visit from the 18-month mark post-accreditation, to between the 36- and 48-month marks of a 5-year accreditation period. |
| Domain 6, page 56-57 | | We have had a policy for declaring potential conflicts of interest *specifically for guideline authors* for a couple of years now, which has recently been reviewed for improvement.<br><br>There is no mention of either the different types of COIs (personal financial, non-personal financial, personal non-financial, personal family interests) or distinction between ***specific*** and ***non-specific*** COIs in any of the conditional clauses, as per NICE's own COI policy document (also, please see "General 2" below).<br><br>All our guidelines are developed without any external funding and this is stated in our current guideline development process manual and will be stated in the updated version. Therefore, we think this would negate the need to explicitly state the funding mechanism in the guideline document itself, as proposed in the new draft process manual.<br><br>*"An explicit conflict of interest statement from all individuals involved in the development of guidance"* in the guideline document itself may be overkill in our opinion. We currently hold these records internally, and summarise each individual's declared COIs, for example:<br>**XX:** 1) sponsorship to attend conferences – Almiral, Janssen, Leo Pharma (non-specific), 2) consultant for Alliance Pharma (non-specific)<br>**YY:** invited speaker – Pfizer<br>**ZZ:** consultant for Novartis (non-specific)<br><br>Also, we do not list those individuals who have declared no COIs as it will be obvious from the summary of those who have, by default.<br><br>We would like to seek clarification on the statement that any COI should be "up to date (e.g. 3 year period)" – is this period the gold standard? We recently changed this "washout period" from 3 years to 12 months to align ourselves with NICE's own COI policy document.<br><br>Whilst we agree that it would be best practice for the chair and co-chair of a GDG to have no COIs at all, in practice we think that this should perhaps be clarified and broken down by the types of COI and their ***specific*** or ***non-specific*** nature.<br><br>We do not fully agree with the clause *"Members of the group should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by the guideline recommendations"*. In certain areas it is almost impossible to get experts who are keen in guideline development but have not participated in or influenced advisory board discussions. One way of overcoming this potential COI is to ensure that the |

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| | | constituents of a guideline development group (GDG) is such that >50% are without any ***specific*** COIs (as per one of the clauses on pages 56-57).<br><br>We would also like to seek clarification on what is meant by "personal professional interests" as we deem this to be equivalent to "personal non-financial interests" whereas the new draft process manual elaborated this COI category as being "personal professional *financial* interests". |
| General 1 | | For future reference it would be most helpful if the "Key changes to the manual" document could point to the relevant pages on the new draft process manual. |
| General 2 | | As a result of the launch of the new NICE website, none of the links in the new draft process manual works. |

**Please email this form to:** accreditation@nice.org.uk

**Closing date: 5pm on Thursday 26 August 2014**

**PLEASE NOTE:** NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.