

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
CENTRE FOR HEALTH TECHNOLOGY EVALUATION
MEDICAL TECHNOLOGIES EVALUATION PROGRAMME

Interim process and methods statement for the production of Medtech Innovation Briefings (MIBs)

1. Introduction

1.1 Introduction to interim process and methods statement

This integrated process and methods statement describes how Medtech Innovation Briefings (MIBs) are developed. It provides an overview of the key principles and describes main stages of development for MIBs. The statement is designed to ensure that robust, quality-assured briefings are developed for the NHS in an open, transparent and timely way, with appropriate input from key groups.

1.2 Background to Medtech Innovation Briefings

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. Further information about NICE and its work is available on the NICE website (www.nice.org.uk).

The NICE Medical Technologies Evaluation Programme (MTEP) identifies and selects medical devices and diagnostic technologies and routes them to appropriate evaluation programmes at NICE. It also develops guidance and advice on the effective and cost efficient use of these technologies for the NHS and its social care partners, and where appropriate, commissions research on the clinical utility of technologies with an underdeveloped evidence base.

MIBs provide a description of the technology, including its likely place in therapy, the costs of using the technology and a critical review of the strengths and weaknesses of the relevant published evidence. Their purpose is to provide a rapid service that gives objective information on device and diagnostic technologies to aid local decision-making by clinicians, managers and procurement professionals. By making this information available, NICE helps to avoid the need for NHS organisations to produce similar information for local use.

MIBs are not NICE guidance. They differ in format, contain no judgement on the value of the technology and do not constitute a guidance recommendation.

2. Medtech Innovation Briefings

2.1 Aims

The aim of MIBs is to provide objective information on medical technologies as an aid to local decision-making by clinicians, commissioners and procurement professionals. They may also be of interest to patients and the public. Production of a MIB does not preclude topics being notified to MTEP, and subject to its usual processes, being selected and routed for guidance development.

2.2 Key audiences

MIBs are produced for:

- clinicians and managers, to inform their decision-making
- local decision-making groups involved in commissioning, policy development, or individual funding requests (IFRs), for example, within a Clinical Commissioning Group (CCG) or NHS Trust;
- they may also be of interest to patients and the public, to help inform treatment choices.

2.3 Key activities

The key activities involved in the production of each MIB are:

- identifying, prioritising and selecting the topic
- describing the technology and its potential use in the treatment pathway
- summarising the published evidence and technical information
- critically reviewing the strengths and weaknesses of the evidence
- placing the evidence in the context of the wider evidence base for the management of the condition for which the technology is being considered (particularly NICE guidance, if available)
- highlighting potential implications for local decision-making or clinical practice.

3. Who is involved in producing MIBs?

3.1 The Medical Technologies Evaluation Programme

The MTEP is part of NICE's Centre for Health Technology Evaluation. The MTEP team consists of an Associate Director and technical, project and administrative staff. For MIBs, the team is responsible for:

- identifying potential topics for MIBs, both from information NICE is aware of and from external sources, chiefly, NHS England
- commissioning from the External Assessment Centre MIBs that are developed and prepared for publication in line with the agreed process and standards
- liaising with the External Assessment Centre to identify external specialist commentators to help ensure the content is relevant and useful
- providing quality assurance of the content of MIBs and ensuring timelines for production are followed
- developing and reviewing processes and methods for producing MIBs.

3.2 Provider of MIBs - External Assessment Centres

NICE holds a contract with External Assessment Centres (EACs) that author MIBs to an agreed process and standard. MTEP manages the contract with the EACs. In summary, the role of the EAC is to search for and sift the evidence, critically appraise the evidence, develop a draft MIB and involve specialist commentators. This process, and the arrangements for working between the EACs and MTEP, is described in section 5. EACs are required to comply with the NICE code of conduct on conflicts of interest, and undertakings on confidentiality. For more information about how NICE deals with conflicts of interest, please see '[A code of practice for declaring and dealing with conflicts of interest](#)' on the NICE website.

3.3 The NICE Public Involvement Programme

Where appropriate, the Public Involvement Programme (PIP) provides NICE with advice on the likely impact of a particular medical technology for patients or their carers. The role of the PIP team in the development of MIBs is to provide a short commentary, based on their experience and expertise. For some technologies, no commentary will be possible, because patients or carers may not have any direct involvement with the technology. Where appropriate, the External Assessment Centre will incorporate any commentary from the PIP in the MIB.

3.4 Other NICE groups and teams

The MTEP team works closely with members of other NICE guidance teams to ensure that MIBs are set accurately in the context of published, planned or proposed NICE guidance, including reviews and updates.

The MTEP team also works with the NICE Communications team, which carries out an editorial review, and publishes and highlights the MIBs.

The NICE Guidance Executive approves each MIB for publication.

3.5 MIBs Stakeholder Group

The MIB Stakeholder Group has a standing membership, consisting of representatives from NICE, from each of the main industry bodies and NHS organisations (including NHS England). The MIB Stakeholder Group will initially meet quarterly and thereafter will decide on the appropriate frequency of meetings to ensure stakeholders are kept up to date.

3.6 Specialist commentators

Specialist commentator(s) are identified by the EAC. They are practitioners who have experience in the therapeutic area for which the medical technology is to be used. Their role is to provide information on the potential use of the technology in the treatment pathway, clarify any issues about the reviewed evidence and comment on any issues which may arise from the practical application of the information contained in the MIB. They also review draft MIBs before publication. The EAC may identify appropriate specialist commentators from existing NICE networks, the sponsor and national professional organisations. For each MIB, the EAC seeks from each specialist commentator a declaration of interests and an undertaking on confidentiality, using its existing organisational policies and procedures on managing conflicts of interest and confidential data.

3.7 Manufacturer

When a technology is identified for the development of a MIB, NICE informs the manufacturer (or distributor, depending on the UK marketing arrangements) of its intention, and the expected timeframe for production, giving as much notice to the manufacturer as possible of its intentions. The External Assessment Centre invites the manufacturer to provide relevant information to support the production of the MIB.

The manufacturer is also invited by the External Assessment Centre to comment on the draft MIB within an agreed timeframe. The manufacturer has the opportunity to comment on matters of factual accuracy, and respond to any specific questions from the External Assessment Centre about the information they submitted to inform the development of the MIB.

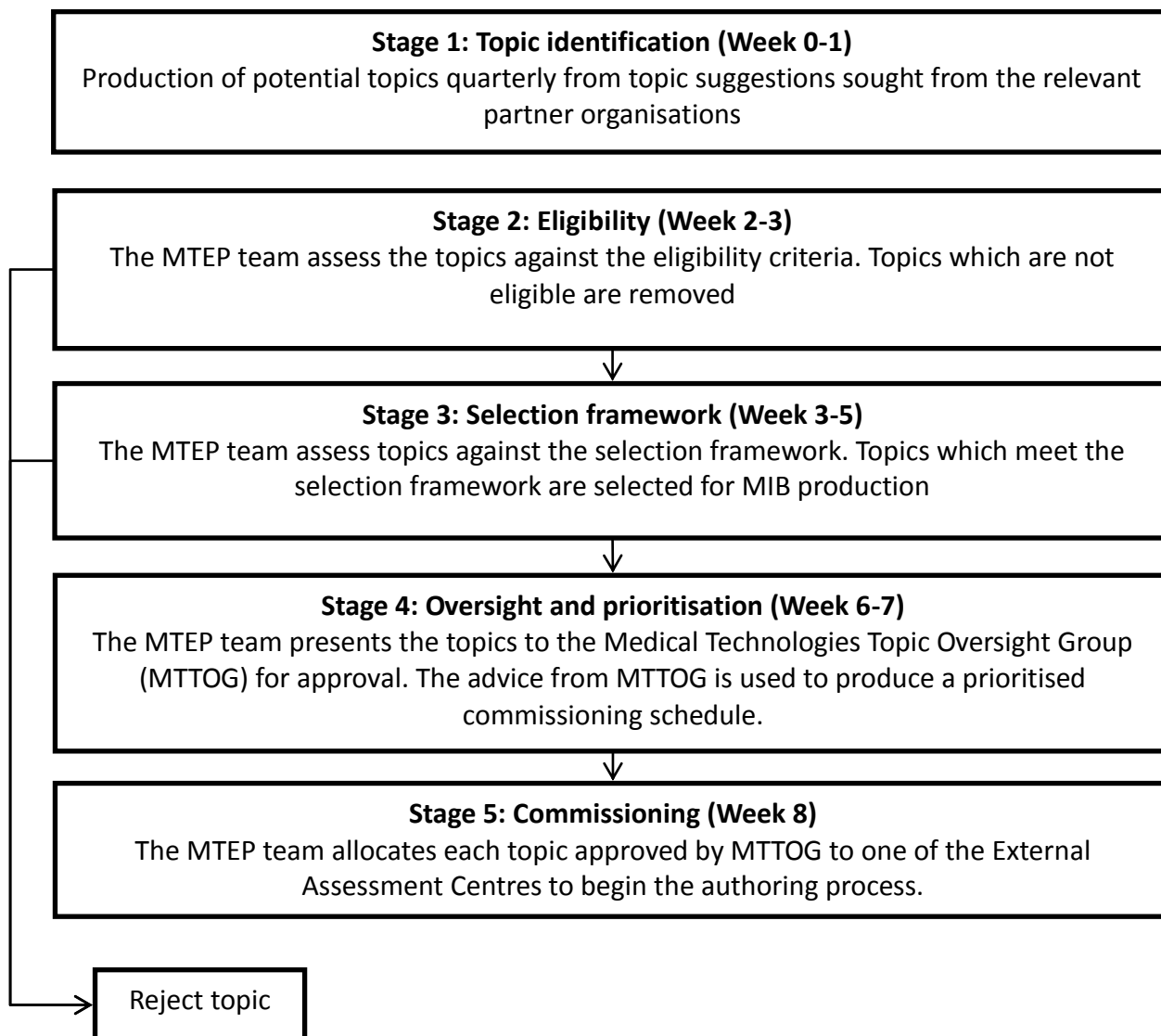
3.8 The Medicines and Healthcare products Regulatory Agency (MHRA)

The External Assessment Centre contacts the MHRA to check the regulatory status of the technology and ask for any information or evidence held on file that is not confidential. The MHRA is invited to comment on a draft MIB within an agreed timeframe, in relation to regulatory and safety issues within the topic covered by the MIB.

4. Topic identification, eligibility, selection and prioritisation

The process used for the identification, eligibility checking, selection, and prioritisation of topics is operated by the NICE Medical Technologies Evaluation Programme and is summarised in Figure 1.

Figure 1: Main steps in the process for topic identification, selection, and prioritization for MIBs



Stage 1: Topic identification

In general, potential topics will be identified where there is a need for information about the technology. In addition to the MTEP team’s routine engagement activities with individual manufacturers, topics may be identified from a range of sources, including but not limited to:

- NHS England: MTEP meets regularly with representatives from NHS England to receive topic suggestions.
- The National Institute for Health Research Horizon Scanning Centre, at the University of Birmingham, has extensive experience and expertise on horizon

scanning of health care technologies including devices and diagnostic tests and is approached to identify suitable medical technologies.

- Partner organisations are approached from time to time, normally quarterly, to suggest potential topics.

Sources from which topic suggestions are sought are recommended to consider the selection framework and the exclusion considerations in Box 1 below when suggesting topics. These considerations are designed to filter topics unsuitable for development into a MIB. All topic suggestions, move to Stage 2.

Stage 2: Eligibility

Each suggested potential topic is considered by the MTEP team against the following eligibility criteria:

- The technology is a medical device or diagnostic test that falls within the scope of the EU Medical Devices and In Vitro Diagnostics directives, this includes devices used in social care that are eligible within this definition.
- The technology has a CE mark or equivalent regulatory approval or, if not, this is expected within 12 months*.
and
The technology is available to the NHS, or the manufacturer has plans in place for the launch of the technology in the NHS.
- The technology is either new or an innovative modification of an existing technology with claimed benefits to patients and the NHS when judged against the comparator(s).
- The technology does not fall under the responsibility of a separate national guidance producing body (e.g. National Screening Committee).

Topics which are not eligible do not proceed to Stage 3.

Stage 3: Selection Framework

The MTEP team undertakes an assessment of the remaining topics against the inclusion and exclusion considerations for MIB selection and identifies those topics which are selected for MIB production and progress to Stage 4. These topics are shared with NHS England.

* To be eligible for acceptance into the programme the technology must CE marked (or expect to be CE marked) as either; a medical device (under EC directive 2007/47/EC), an active medical device (under EC directive 90/385/EEC), an active implantable medical device, (under EC directive 90/385/EEC) or an in vitro diagnostic medical device (under EC directive 98/79/EC). Please refer to our [process guide](#) for a more detailed description.

<p>Box 1 : exclusion considerations</p> <ul style="list-style-type: none"> • NICE guidance, or high-quality, up-to-date reviews, are already available from a NICE accredited source • The technology would be more appropriate for NICE guidance than a MIB 	<p>Box 2 : inclusion considerations</p> <ul style="list-style-type: none"> • There is demand for the information from the NHS (NICE considers the volume of requests for information on, or level of clinical interest, in the topic) • There appears to be potential for useful clinical outcomes, quality of life, and/or cost impact • There are some data or evidence, relevant to the technology, which can be made publicly available, on the technology to summarise and critically appraise
---	---

Stage 4: Oversight and prioritisation

The MTEP team presents suitable topics to the Medical Technologies Topic Oversight Group (MTTOG) which ensures that the selection framework has been consistently applied.

It is anticipated that production capacity will normally be sufficient to meet the demand for MIBs in any one period. Based on advice from MTTOG, MTEP produces the commissioning schedule, which allocates topics to the next available External Assessment Centre slot. If in any one period there are more topics than capacity to produce the MIBs, MTTOG advises MTEP on the prioritisation of the commissioning schedule, largely based on the importance of the topics to the NHS, and in discussion with NHS England where necessary. NICE informs the manufacturer of the intention to commission a MIB at this stage, in order to enable them to plan to meet a future request for information from the EAC.

Stage 5: Commissioning

The MTEP team allocates each topic approved by MTTOG to one of the EACs to begin the authoring process.

Once the MIB topics are approved, and the process steps in week 1 have been completed (shown in Table 1), the topics are added to the list of MIBs in development on the NICE website (link to be added), and the confirmed development timeline is sent to the manufacturer.

5. Production

5.1 Equality and diversity considerations

MIBs are developed in accordance with the [NICE equality scheme](#). Each MIB contains information on any potential equality issues raised by the use of the technology.

5.2 Process and timescales

Table 1, overleaf, shows the key steps in the development of MIBs.

Table 1 Key steps for developing a MIB

Key step	Responsible party	Completed by
Topic commissioned from EAC	NICE	Week 0
Scope topic, identify topic issues and specialist commentators	EAC	Week 1
Contact manufacturer and regulator for data	EAC	Week 1
Literature search	EAC	Week 1
Searching for evidence	EAC	Week 1
Sifting and selecting the evidence		Week 2
Reviewing and categorising the evidence		Week 2
Authoring the MIB:	EAC	Week 4
Produce initial draft of MIB		
Preliminary technical check of initial draft by EAC	EAC	Week 4
Review of draft MIB:	EAC	Week 5
Initial draft sent to manufacturer, MHRA, specialist commentator (s) and PIP for review		
Review comments received and revised draft produced	EAC	Week 7
Quality assurance of the MIB:	EAC	Week 8
Technical and editorial check of content by EAC		
Revised draft sent to NICE	EAC	Week 8
Edit MIB	Editors	Week 9
Final check of content by MTEP Associate Director/Programme Director	NICE	Week 10
Publication of the MIB:	NICE	Week 11
Approval to publish by Guidance Executive		
Send MIB to manufacturer for final fact check	NICE	Week 11
Publication on NICE website (a MIB may be published at any time)	NICE	Week 12

5.3 Initiation of individual topics

The MTEP team meets the EAC to which the topic has been allocated to initiate the production process. The initiation confirms the following:

- The technology, target population and indication including any potential equality issues
- The arrangements for contacting commercial organisations (manufacturer, distributor and/or agent)

- The arrangements for contacting the MHRA to obtain evidence held on file that is not confidential
- The arrangements for specialist commentator input
- Where appropriate, the input that will be provided by NICE's PIP (see section 3.3)
- Terms for a literature search to identify published clinical data that reflect the indication for the medical technology
- Arrangements for identifying:
 - regulatory status
 - relevant published studies, or other data on the medical technology
 - evidence of clinical effectiveness for the medical technology in the condition under consideration
 - safety issues, encompassing key adverse events, precautions and contraindications
 - incidence and prevalence of the condition, what treatment alternatives exist and possible sources of information on estimates of current medical technology usage
 - cost of the medical technology and the cost of alternative treatment options.

5.4 Contacting the manufacturer/distributor and the MHRA

The EAC asks the manufacturer to support the production of the MIB by providing any of the following data it holds (within 10 working days):

- Regulatory information including:
 - Licence status within the European Union or the UK
 - The CE certificate or confirmation that CE marking is expected within 12 months
 - Confirmation of the class of medical device in which the technology is approved, or expected to be approved
- Description of the technology and its mechanism of action, including brief details of what the technology comprises, consumables required, etc. (if relevant)
- Cost details (including the list price of the technology and any consumables etc.)
- Description of the indication, its intended purpose, and way in which the technology would change current management in the NHS
- Description of the target patient population
- Key published clinical studies relating to the indication being reviewed in the MIB and information regarding ongoing or recently completed studies
- The extent of its use in the NHS, if known, or best estimate from the available data
- Depending on the technology, the EAC may request additional information.

The External Assessment Centre seeks further clarification, at any time, about information provided by the manufacturer. This ensures flexibility in cases where the request for information is unusually large, complex or non-routine

The External Assessment Centre also contacts the MHRA to ask for any evidence or information on file that is not confidential.

Both the manufacturer and the MHRA are sent the timelines for the production of the MIB, including the deadlines for receipt of data and the expected dates for the fact check process on the draft MIB.

5.5 Literature search

5.5.1 Searching for evidence

The EAC conducts a literature search according to the agreed scope and strategy. The search strategy is documented and included in the published MIB. Quality assurance for the search process is also documented.

The literature search is designed to identify the highest quality available published evidence relating to the clinical effectiveness of the medical technology. In addition, the search strategy makes explicit reference to information in the instructions for use relating to the intended use of the technology, precautions, warnings and undesirable effects and also to published advice from the MHRA (or the Food and Drug Administration [FDA] if there is no relevant MHRA advice). Cost information is obtained primarily from the manufacturer or from other sources as needed (such as the Drug Tariff, where the device or diagnostic test is included), NHS Supply Chain or by seeking intelligence from local NHS procurement specialists.

5.5.2 Sifting and selecting the evidence

The EAC sifts the final set of search results using the title and abstract of each article, applying first exclusion and then inclusion criteria. These include the basic criteria as set out below.

First sift

This process removes evidence based on the following exclusion criteria:

- articles of poor relevance against search terms
- publication types that are out of scope:
 - non-English language studies
 - conference abstracts[†]
 - review protocols (for example, Cochrane review protocols)
 - articles if neither the abstract nor full text is freely available online.

Second sift

This sift of evidence includes relevant primary research that addresses the use of the medical technology within the defined indication under review. If robust randomised controlled trials or systematic reviews are available, they form the primary basis of the review of effectiveness. However, given the known characteristics of the evidence base for medical technologies, the best available evidence on which to produce the MIB will often include other study types.

The EAC records the reasons for inclusion and non-inclusion based on the second sift, as well as a 'long list' of those studies that are excluded from the first sift which will be available on request.

[†] Studies that have been reported only as conference abstracts or otherwise not reported in full may be included in a MIB but cannot be critically appraised. Such evidence should be interpreted with caution. The MIB may indicate if key clinical trials are ongoing or have been completed but not yet published in full.

5.5.3 Appraising and categorising the prioritised evidence

The EAC prioritises the evidence for critical appraisal and records the reasons for any exclusions. The full text of the prioritised evidence is appraised using an [assessment form suitable for the type of evidence](#).

5.6 Authoring the MIB

The External Assessment Centre drafts the MIB using a standard template, which includes sections relating to the following:

- a summary of the regulatory status of the technology including:
 - the intended use/purpose
 - the setting and intended user
- key points from the evidence
 - a summary of the clinical benefits and cost implications
 - a list of the key evidence for the clinical benefits and cost implications
- details of the intervention, including:
 - general information about the disease or condition and its incidence and prevalence
 - alternative treatment options with links to relevant guidance/evidence
 - usage and cost
 - comments and insights from external specialist commentators on the treatment pathway and likely place in therapy
 - where appropriate and available, a short commentary on any significant impact for patients or their carers
- a detailed review of the available evidence, with relative strengths and weaknesses of evidence and the evidence selection process.

5.7 Reviewing the draft MIB

The EAC sends the draft MIB to:

- the external specialist commentators: at least three specialist commentators are invited to comment on each MIB;
- the manufacturer, for factual accuracy checking;
- the NICE MTEP team, for process and methods quality assurance purposes;

The draft MIB is also sent for comment to the NICE PIP and NICE costing teams.

Any comments received, and actions considered or taken, are recorded by the EAC[‡] and incorporated within the production of the revised draft.

[‡] This information is available on request from NICE
Page 12 of 15

5.8 *Quality assurance, final production steps and approval to publish*

5.8.1 Quality assurance

Initial quality assurance of the MIB is carried out by the EAC. This involves a detailed check of all content, to ensure all sections of the document contain statements and conclusions that are fair and balanced. The EAC is responsible for checking that MIBs accurately reflect the evidence reviewed and are substantiated by an explicit and appropriate source of evidence. This is carried out to a checklist provided by NICE which includes a check that the technology (if commissioned prior to CE marking) has received appropriate regulatory approval. NICE will not publish a MIB on a technology which does not have a relevant CE mark. A further check for clarity, grammar, spelling and style is also undertaken by the EAC. All drafts and any changes to drafts are recorded for audit purposes.

5.8.2 Final production steps

The EAC sends the revised draft MIB to the NICE MTEP team, who, in conjunction with the NICE publishing team, review it and produce a publication draft. The manufacturer is sent the publication draft and is given four working days to check for factual errors. Any necessary corrections are made by the MTEP team, with advice from the EAC if needed. The manufacturer is notified of the date of the fact check of the publication draft when the topic is commissioned.

5.8.3 Approval to publish

The Programme Director signs off the MIB which is presented to NICE's Guidance Executive with: relevant briefing on the project history; key issues from the authoring; and a recommendation by the MTEP team to publish the MIB. After publication is approved by Guidance Executive, the manufacturer is informed of the scheduled publication date, and may request an embargoed copy of the MIB to be sent to them 24 hours before publication. Provision of an embargoed copy will be subject to a confidentiality undertaking and agreement.

5.9 *Publication*

The final MIB is uploaded and made available online through the NICE website.

The NICE Communications team develops a communications plan for the MIB, together with the Associate Director within MTEP, and is responsible for disseminating the MIB once it has been published.

6. Lifespan of MIBs

Every MIB states the date of its publication. The decision whether or not to update or withdraw published MIBs is considered on a regular basis by MTEP in the light of its current awareness activities. Examples of circumstances when withdrawal of a MIB might be required include:

- NICE is publishing guidance on the use of the medical technology in the stated indication;
- the technology is no longer available to the NHS;
- the occurrence of a significant safety issue .

If significant new evidence becomes available on the technology after publication of the MIB, NICE may liaise with the manufacturer to discuss potential notification of the technology to be considered for potential guidance development, following NICE's normal process.

7. About this interim process and methods statement

The interim process and methods statement for MIBs provides a high-level overview of the process for developing MIBs and will be supported by a series of technical guidance notes, templates and a Frequently Asked Questions guide. The interim statement will be reviewed in approximately 12 months, in the light of early experience.

For published MIBs, see the NICE website (www.nice.org.uk/mib).

Appendix A

Publication history:

Version	Date	Changes made
1	01/12/2013	Original version published on NICE website
1.1	10/03/2014	The hyperlink to the NICE equality scheme corrected The final manufacturer fact check moved to after Guidance Executive approval Additional time provided for manufacturer to undertake final fact check Clarification provided on the application of the Selection Framework for MIB topics.