UK Health Security Agency

Specialised Microbiology and Laboratories

Standards Unit

UK STANDARDS FOR MICROBIOLOGY INVESTIGATIONS

DEVELOPMENT PROCESS

CONTENTS

SECTION 1.0 **INTRODUCTION**

The UK Standards for Microbiology Investigations (UK SMI) development process is intended for use by staff in the Standards Unit and is released to other parties for information only. The process should be used in conjunction with the SOPs and work sheets noted throughout the document and stored on Q-pulse.

The development process has been accredited by National Institute for Health and Care Excellence (NICE) and certified to ISO 9001:2015 standards. UK SMI development should follow the process indicated in this document in order to display the NICE accreditation mark or statement.

SECTION 2.0 **UK SMI AIMS**

1. To provide good quality evidence based, NICE accredited standards for the investigation of infections for diagnostic and public health microbiology laboratories, without commercial company bias or emphasis.
2. To develop overarching documents based on the investigation of syndromes which in turn are supported by more detailed guidance on the investigation of diseases / infections.
3. To develop, review and update UK SMIs through a wide engagement and consultation process where the views of all participants are considered, and the resulting documents reflect the majority agreement of contributors.
4. To advise commissioners of microbiological services on the range and standard they should require in their contracts with microbiology laboratories.
5. To provide the UK SMIs electronically as a ‘one-stop-shop’ for microbiology investigations

SECTION 3.0 **BACKGROUND**

UK SMIs is a referenced collection of clinical microbiology[1] standards consisting of approximately 100 documents. UK SMIs have been developed since 1996 by working groups of experienced laboratory-based medical and scientific

[1] Microbiology is used as a generic term to include the two GMC-recognised specialties of Medical Microbiology (which includes Bacteriology, Mycology and Parasitology) and Medical Virology.

microbiologists from throughout UKHSA and NHS. It is not mandatory for UKHSA and NHS laboratories to follow UK SMIs but it is encouraged for all laboratories (UKHSA and NHS) to use the broad outline so that good practice can be maintained across the country.

UK SMIs provide a good quality standard for the investigation of infections in diagnostic and public health microbiology laboratories and are widely accepted by microbiologists in the UK as an important resource supporting good practice in microbiology laboratories. Each document is based on evidence where available and existing good practice where evidence is not available. Documents undergo a wide consultation process involving staff in microbiology laboratories and other experts are consulted where appropriate to ensure good practice is reflected in the standards.

Each document is developed or reviewed by staff in the Standards Unit and scheduled for discussion at a UK SMI Working Group meeting. The meetings are held at regular intervals throughout the year to discuss UK SMIs and issues affecting laboratory standards and best practice. UK SMIs are developed in equal partnership with partner organisations on behalf of all microbiologists in the UK, as well as including Patient and Public Involvement (PPI). PPI representation is drawn from the UKHSA Peoples Panel and follows the UKHSA process for PPI involvement. All UK SMI working groups are overseen by and report to the UK SMI Steering Committee.

The Steering Committee membership is drawn from the relevant professional disciplines and includes a Chairperson, UKHSA Standards Unit scientific staff and representatives from partner organisations, as well as a Patient and Public Involvement. The representatives should be members of the council (or equivalent body) of the partner organisations and should therefore give representative views of the council and the majority of members. Representatives act as conduits for two-way reporting and dialogue from and to their representing partner organisation.

The final UK SMI document may be utilised exactly as published or used as a template for local adaptations. Such flexibility offers savings in time and resources at the local level while assuring good governance. Where local protocols differ significantly from UK SMIs, laboratories should justify the

changes within their local systems.

UK SMIs are educational and encourage participating laboratories to retain an enquiring attitude. In addition, they are designed to help ensure that laboratories provide a good clinical and public health microbiology service.
UK SMIs are freely available on an open access website as controlled documents; they can be viewed online.

Development of overarching documents based on the investigation of syndromes is an ongoing initiative and will be supported by guidance on the investigation of diseases / infections. The aim of this initiative is to provide a suite of documents available electronically as a 'one-stop-shop' for microbiology investigations. This will have the benefit of re-aligning the advice to fit more closely with the public health agenda and identify gaps in the document repository.

UK SMIs cover all stages of the investigative process in microbiology from the pre-laboratory processes (pre-analytical stage), laboratory processes (analytical stage) and post-laboratory processes (post-analytical stage). They comprise a collection of recommended syndromic algorithms for initial test selection, standard operating procedures for carrying out microbiology and virology tests, together with testing and confirmatory strategies. In addition, quality guidance documents are written to describe essential laboratory methodologies which underpin quality.

The UK SMIs are reviewed and updated every 3 years[2] or earlier if necessary, to reflect changes in current practice.

UK SMIs represent a good standard of practice to which all laboratories undertaking microbiology investigations should be expected to work; they neither represent minimum standards of practice nor do they necessarily describe the highest level of complex laboratory investigation possible.

SECTION 4.0 QUALITY STANDARDS/ACCREDITATION

The process underpinning the development of UK SMIs includes methodologies for writing and updating the documents and is certified to ISO 9001:2015. The

[2] Reviews can be extended up to 5 years where appropriate.

development process for UK SMIs has been accredited by NICE since 2011.

SECTION 5.0 QUALITY SYSTEM

The development process is subject to audit by a Quality Assurance team (internal to the organisation but external to SU), external ISO assessment and revalidation audit by NICE. In order to assure continuing suitability and effectiveness, the Standards Unit Quality System is reviewed formally at least once a year at the Annual Management Review (AMR). Records of the review including decisions and follow up activities are kept in the minutes of each AMR meeting.

The quality system for UK SMIs is described in S9304 – Management of UK SMI Quality system and other associated standard unit activities.

Document Control System for UK SMIs

The document control system ensures the development stage of each document is easily identified by category, number, draft version, or issued version (see S9306 – Document control system for UK SMIs for further information).

Checklist Database

Checklist database contains all the information regarding a documents development and is maintained by the lead scientist who produces reports from the database for meetings. The Checklist database provides data to demonstrate how timelines are met. This is presented at the annual management review.

Control of Change

Significant changes to the development process are listed in a systematic way on the UK SMI Control of Change spreadsheet (see SW3024). Changes to processes are discussed in Standards Unit meetings. Changes are recorded in the meeting minutes and the details are updated on the control of change spreadsheet.

Error Log

Errors are recorded in the Error Log spreadsheet (SW3024) so that the number and type of error encountered can be monitored and areas for improvement identified. All errors are added to the spreadsheet. and discussed at the Standards Unit meetings.

Risk Register

A Risk Register is a Risk Management tool commonly used in organisational risk assessments. It acts as a central repository for all risks identified by the project or organisation. The Standards Unit risk register (SG184) is document-controlled and can be accessed on Q-pulse. It is reviewed in accordance with the dates set for each risk and discussed regularly at Standards Unit meeting.

Policy for Review Timescales

When a document is issued, a summary timeline is produced using the SW 3105 template and this is discussed at a Standards Unit meeting. The following timescales for delivery of UK SMIs cover the initiation of review or draft to the date of issue:

Under review documents - reviewed within approximately 12 months

Stage	Days	Breakdown
1	5	Preparation of document and references
2	275	Including reference assessment, consultation (4 week slots) and working groups
3	85	45 days with editor 40 days with unit pending issue

Draft documents – completed within approximately 24 months

Note: The timescales quoted are based on adequate resources and reaching a consensus decision. If resources fall or consensus cannot be reached, then the document delivery time is extended.

SECTION 6.0 RETENTION POLICY AND CROWN COPYRIGHT FOR UK SMIS

Draft, issued (current and superseded) are retained indefinitely as follows:

Draft versions of UK SMIs (before issue) – Electronic draft documents are archived on the ESL Archive drive and kept indefinitely.

Issued (current and superseded) UK SMIs - are kept indefinitely in the ESL Archive drive and Q-pulse.

Refer to the UKHSA record retention and disposal schedule (on UKHSA Pulse)

for further details on relevant legislation and guidance followed.

Crown copyright - all website publications are trawled by Legal Deposit Libraries using a special ‘crawling’ software – this effectively enables us to meet with deposit legislation requirements (the 2003 Act) without taking positive action ourselves (except where password protection applies). Accordingly, any and all content placed on GOV.UK is compliant.

File Backup

Backup of shared drives is managed automatically by the UKHSA IT department and consists of two backups made daily. These can be accessed by right clicking a folder, selecting 'Properties' then selecting the 'Previous Versions' tab (refer to S9304).

The process for document recall

Substantive Error

UK SMIs found to be non-conforming due to a substantive error will be recalled. The identified UK SMI will be removed from the webpage. A message will be placed to ask users to contact the Standards Unit in the interim period until the document is corrected and re-issued as a whole integer change and any changes will be detailed in the amendment page.

Non-substantive Errors

Changes that result in a point change do not require notification and hence do not have a message placed on the webpage. Changes of this kind are to be carried out as soon as possible. Evidence explaining the reason for a point change should be attached to the relevant Q-pulse record.

Summaries of non-conforming UK SMIs are reviewed at Management Review meetings. Where appropriate, recommendations for corrective and/or preventive actions are made.

The process for document withdrawal

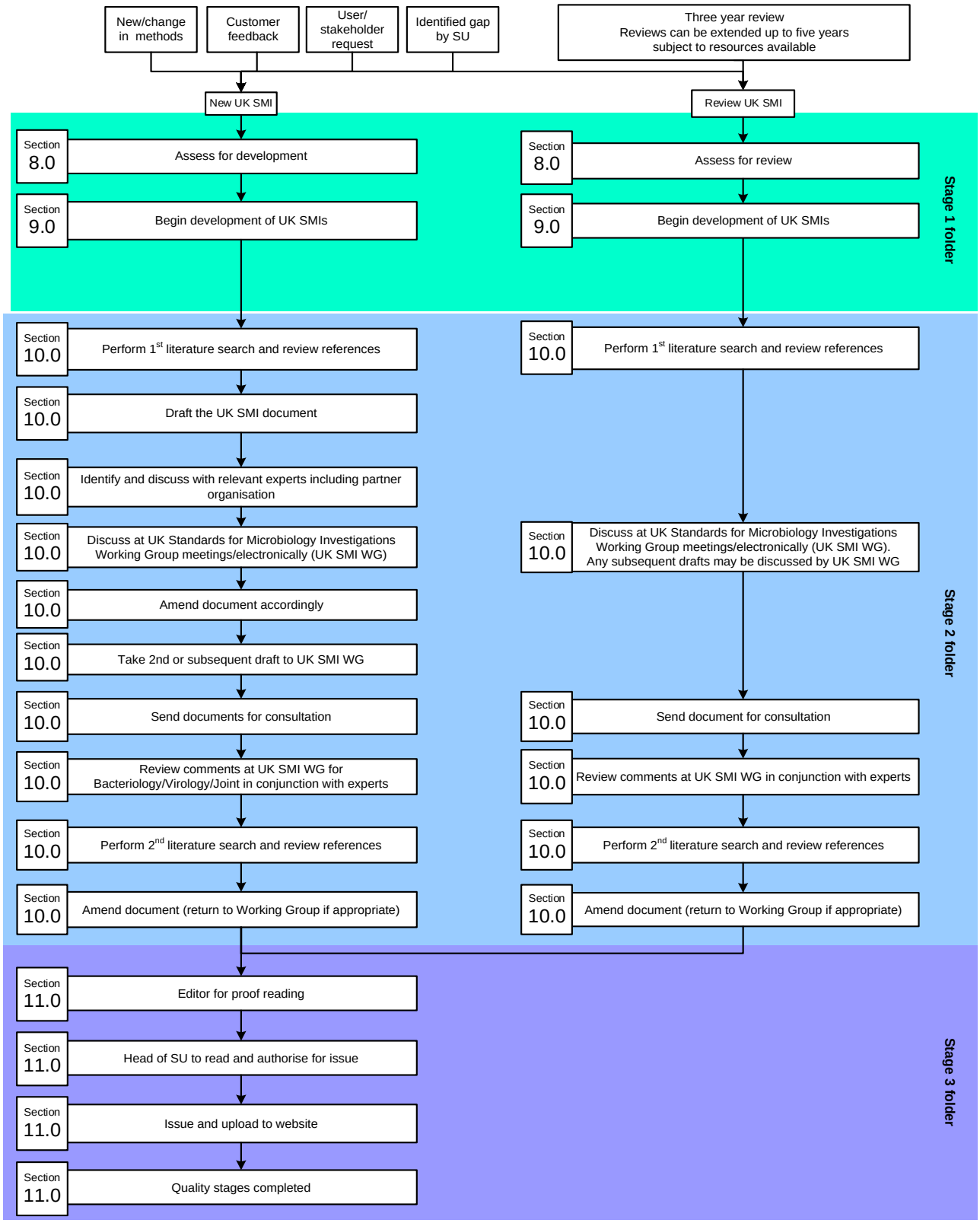
UK SMIs deemed no longer fit for purpose and the methods or contents no longer valid are withdrawn. When a document is withdrawn it marks the end of the document’s lifespan. In these cases, evidence supporting the decision should be saved in Q-Pulse, the website page should be amended to show that the document has been withdrawn.

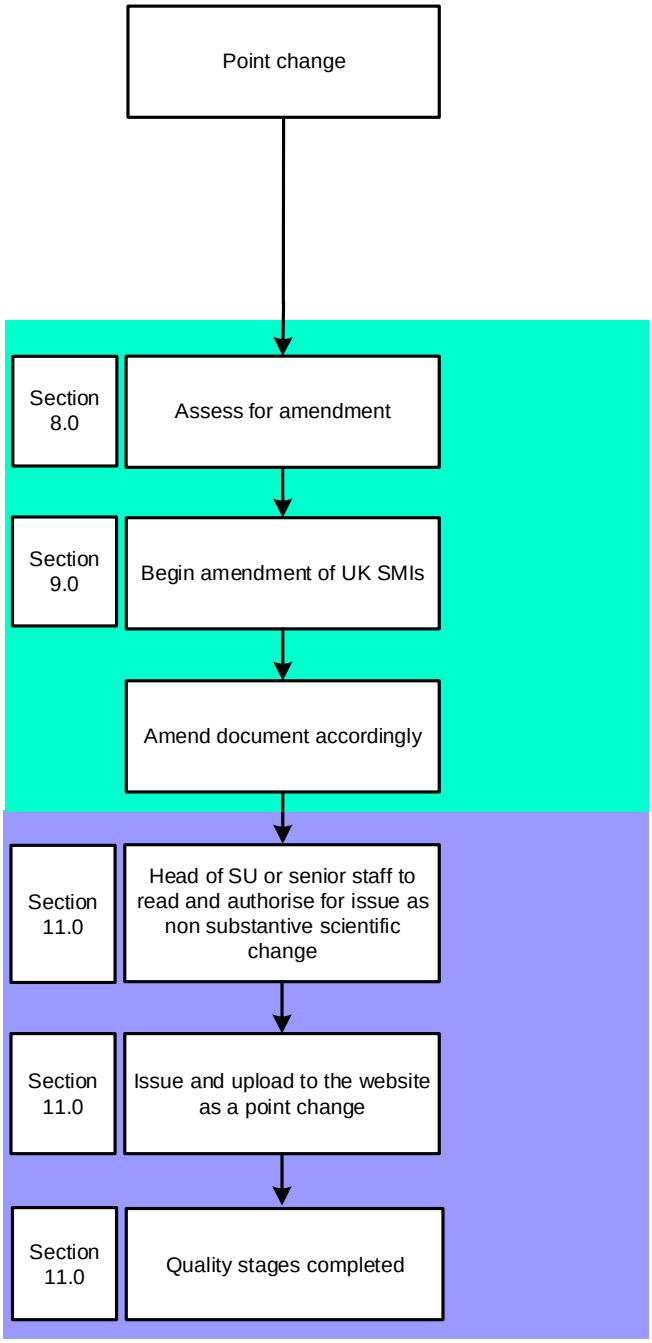
A rationale for the decision to withdraw should be saved in Q-pulse and added to the website (refer to S9315)

Users may request access to these documents, but it must be explained why the document is withdrawn ie out of date, methodology no longer valid or other organisations such as Oxoid have more up to date information etc. The withdrawn document may be sent to a user on request. It should always have a ‘withdrawn’ watermark to indicate that the document is out of date and the covering email should explain that Standards Unit cannot be responsible for the consequences of its use. Where appropriate, advise the user to check details with experts or relevant organisations. For more information see S9304.

SECTION 7.0 THE DEVELOPMENT PROCESS FOR UK SMIS

Detailed flowchart of the entire UK SMI development process





Note: Point changes are minor amendments which do not cause a substantive scientific change to the content.

The point change process also applies to RUCs

SECTION 8.0 PRE-DEVELOPMENT STAGE FOLDERS

START

The development process of a UK SMI begins with either a stakeholder request; change in methodology, customer feedback, or after a 3-year review period[2]. The Steering Committee aim is to oversee, advise and guide the activities of the UK SMI Working Groups and may propose new documents or strategic direction.

Assess and approve for development / review

Listed below are some of the triggers for initiating the development of UK SMI including:

- **Point change** - reasons for a point change are described in S-9306 Document Control System for UK SMIs. A point change will progress from Stage 1 straight to Stage 3 and by-pass Stage 2. A new record in the checklist database should be created for a point change; note that a point change does not change the date of the next full review.
- **Full review/New document** - involves assessing changes in methodology/suggested amendments or whether there is a continued requirement for the document along with the possible impact on existing UK SMIs. Development may be triggered by the following reasons which need to be captured in the checklist database:

    1. **Change in methodology published in peer reviewed journal** – New microbiological technologies eg PCR and microarrays may become the gold standard with supporting publication. The Standards Unit ensure that they are abreast of current developments by undertaking the following activities:
        - Literature search
        - Horizon scanning
        - Meetings/conferences
        - Consulting with experts
        - Consulting with governmental organisations including Department of Health and Social Care (DHSC) and Medicines and Healthcare products Regulatory Agency (MHRA).
        - Consulting with partner organisations
        - Networking

2. **Customer feedback** – The Standards Unit undertake customer feedback by requesting comments on documents for review and at the same time inviting suggestions for any new documents users feel are required or identify gaps in the current UK SMI collection. The suggestions are assessed by members of the Standards Unit and where necessary the UK SMI Working Groups. Where there is a business need a customer survey may be undertaken.
3. **User proposal** / **interested parties request** – Requests for changes in UK SMIs may come from users of UK SMIs by email or through consultation. The suggestions are assessed as described in the customer feedback section above.
4. **3-year review cycle**[2] **–** Each document is subject to a 3-year review[2]. The purpose of the regular review cycle is to ensure that the document undergoes a review process and its usefulness/relevance assessed. It is intended that the review take 12 months from the beginning of review ie 3 years + 12 months before the document becomes effective. Chairs of the working groups should be kept informed of timeline progress to help ensure that they are met. A yearly work schedule is produced to ensure reviews are undertaken on the required documents in a timely manner.

When considering a new or reviewed UK SMI, attention should be given to the following parameters:

- Current scientific literature available to support the UK SMI. A literature search should be performed.
- The target audience - members of the Standards Unit assess the need for the UK SMI in the field of microbiology. This can be achieved by carrying out a survey, seeking expert advice from professionals or asking members of the UK SMI Working Groups.
- National policy/guidelines in the subject area.
- Current good practice.
- Check for other groups already developing a similar document to collaborate.

- Health benefits, risks and side effects of the UK SMI should be considered.
- Evidence of the triggers for development of a UK SMI is documented in the UK SMI Development Checklist (SW1001). The evidence may be in the form of minutes of meetings, review schedule or an email.

SECTION 9.0 STAGE 1 FOLDER

To initiate the development of a UK SMI, refer to S9304-Management of the UK SMI Quality System and associated activities. At this time Q-pulse should be checked for any change requests associated with the document that might have been raised. The stages involved that need to have dates recorded on the checklist database are:

- Date document downloaded from the quality system
- Date document formatted and watermark added
- Date a literature search was submitted, and preliminary form populated

A new record for the relevant UK SMI should be created in the checklist database to store this information.

SECTION 10.0 STAGE 2 FOLDER

DRAFTING

Under Review UK SMIs

Reviewed documents are developed to a standard template (S9355) using standard terminology and abbreviations (S9331). Once a UK SMI has been brought under review the nominated Lead Scientist should read through the document to see if there are any obvious gaps or problems which need to be resolved. They should then proceed to carrying out a literature search to obtain the latest scientific information and amending the document as appropriate by reviewing and assessing the references. Track changes and comments are used throughout a UK SMI's review. For under review documents the appropriate working group is asked for comments on the document electronically or at a working group meeting before it is sent for a first round of consultation. Both the initial email to the working group and subsequent correspondence should be

saved in the relevant UK SMI folder on the shared drive. Each consecutive draft version is saved on the Standards Unit shared drive following the agreed document control system (see S9306).

Perform a literature search

When a document comes under review, the overarching keywords associated with the topic are reviewed by the lead scientist. There are two literature searches carried for each UK SMI with the first literature search performed at the start of the review process and second literature search should be performed just before sending the UK SMI document to working group members for final sign off, followed by sending the document to the medical editor (see S9367). A literature search is set up with all identified references downloaded into the preliminary reference assessment form for initial consideration (see S9367). If they are found to be relevant to the content of the UK SMI in question, they are then transferred to the reference assessment form. References are critically assessed to ensure the results are valid, clinically significant and applicable to the subject (see S9332). References which are approved for inclusion in the document are given a SIGN rating and inserted into the document using Endnote software. The review of the references is considered valid for the duration of a UK SMIs review as any significant changes in the field will be identified as part of this process.

Draft document

Having obtained up to date scientific literature the UK SMI can be drafted or reviewed. All draft or reviewed documents are developed to a standard template (see S9355) using standard terminology or glossary of terms (see S9331). Each consecutive draft version is saved on the Standards Unit shared drive following the agreed document control system (see S9306). Draft documents that are discussed at Working Group meetings should be document controlled in accordance with S9306 and if they originate from a member of the group the name of the member whose comments they contain.

The development of a UK SMI is multifaceted and therefore, where relevant, requires the involvement of a range of experts who should be identified in addition to the Lead Scientist in the checklist database:

- Lead Scientist from the Standards Unit

- Related Expert from outside of working group
- Date sent to related expert

WORKING GROUP

There is 1 steering committee and 3 working groups for the development of UK SMIs.

- The Steering Committee for UK Standards for Microbiology Investigations
- Joint Working Group for the development of syndromic algorithms
- Working Group for Microbiology Standards in Clinical Bacteriology
- Working Group for Microbiology Standards in Clinical Virology/Serology

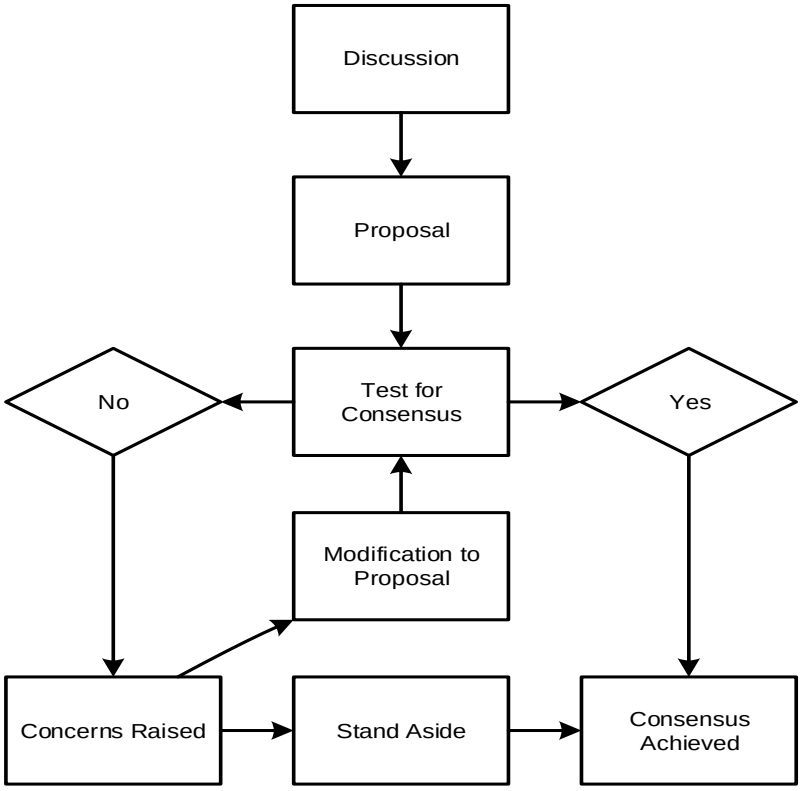
See Terms of Reference (SW3046 and SW3038) for the working groups listed and S9357 **-** Arranging meetings in the Standards Unit for details. There may be occasions when additional working groups need to be set up to complete work on either a short- or long-term basis, sometimes in collaboration. The Chairs of the UK SMI Steering Committee and Working Groups also meet at a Strategy meeting to decide on SU work priorities, to discuss areas of challenges and relevant items to be ahead of the curve. This is an informal touch base meeting which takes place a few times a year.

Working Group members are expected to declare any conflicts of interest or potential bias which may affect the independence of the conclusions or recommendations of the UK SMI (SW3045 and Register of Interests SW3044).

Each UK SMI is discussed and approved by members of the UK SMI Working Group. Members are informed of the dates of meetings as soon as they are available. A certificate of attendance is provided for members to self-certify with either IBMS or RCPath. An outline of working group member's responsibility can be found in SW3038 - Terms of Reference and details on arranging the meetings can be found in S9357.

The role of the Steering Committee and Working Groups is to recommend and develop microbiology standards which are produced to a NICE accredited standard. The Working Groups achieve this by reviewing and writing UK SMIs in line with the Appraisal of Guidelines Research & Evaluation (AGREE) instrument http://www.agreetrust.org/resource-centre/agree-ii/ used for NICE accreditation.

The following consensus decision-making flowchart shows the process followed by the working groups:



Discussions take place on best options for patient care and management by discussing turnaround times for reports, antimicrobial susceptibility testing and treatment options. The financial implications of the recommendations should be considered. The essence of the discussions, all decisions and rationale are noted in the minutes of the meetings.

Amend document

Once comments have been received and agreed from the appropriate experts and members of the working groups the document is updated appropriately. Each draft version will have a document-controlled number as detailed in S9306. Records of changes are available in subsequent versions, annotated notes and minutes of the working group meeting.

Take subsequent draft to UK SMIs Working Group meeting

If necessary, the next draft is taken back to the UK SMI Working group for further discussion. Both the initial email and any correspondence received should be added to the relevant UK SMI folder. The minutes of the meeting should note the next stage for a UK SMI as agreed by the group for example whether to send the

document for consultation (S9315).

CONSULTATION

It is good practice for the documents to be proofread by another scientific member of the Standards Unit other than the person working on the document before it is sent for consultation. The documents normally have a consultation period of 2 weeks as a minimum which could be extended as required (The consultation principles 2018, Cabinet Office). The date the document is sent for consultation, the draft and document number that was sent is noted in the UK SMI checklist (SW1001). If the document undergoes more than one round of consultation the information should be recorded in the checklist. New UK SMIs generally have two rounds of consultation and previously issued documents tend to have one unless significant changes are made as a result of the consensus opinion by the working group. While a UK SMI document is under review, the page for the issued version on the website should be amended to state “Under review” instead of “Issued”; the status on the UK SMI searchable index page should also be updated. A UK SMI uploaded for consultation should have an “UNDER CONSULTATION” watermark. At the end of the consultation period a a watermark should be added to the consultation document giving the dates of the consultation. For more details refer to S9315. If an issued UK SMI requires more than one round of consultation it is generally appropriate to ask targeted questions on the second round.

Review comments at Working Group meetings

Comments from consultation are collected into a ‘Review of Users Comments’ (RUC) document (S9347). Comments that involve basic editing along with other comments that are less controversial or technical are incorporated into the UK SMI straight away. The remaining comments are taken to the working group for discussion, where a final decision is made and the rationale is recorded. All comments are presented to the working group for final sign off. It may sometimes be necessary for further advice from the experts to be sought to validate the working group’s decision. GOV.UK consultation pages are created in Whitehall Publisher, which automatically generates email reminders as the 12-weeks deadline approaches for publication of a consultation outcome. These emails should be forwarded to the scientist leading on the relevant UK SMI document,

and the RUC should be uploaded when ready. If the 12-week deadline is exceeded, then the RUC should be published as soon as possible.

Amend document

The document is amended appropriately and at this point the document either goes back to the group for discussion or goes to the medical editor.

Prepare document for the medical editor

Before the document is sent to the medical editor the following must be completed:

- Proofread (It is good practice for a member of the Standards Unit other than the person working on the document to proofread)
- All grading scores added to the endnote and document
- The amendment table must be completed at this point
- all track changes, highlights and strikethrough of text is removed.

Once the scientific review of the document is considered complete the document is moved to Stage 3 and sent to the medical editor. The checklist should be updated.

SECTION 11.0 STAGE 3 FOLDER

EDITING

The formatting will be checked according to SOP (S9346) and all highlight, track changes and watermarks are removed. The medical editor should receive the final document as close to an issued document as possible hence removal of track changes, highlights and watermark. An electronic copy of the document is sent to the appropriate medical editor (S9304). Contact details for medical editors are on the working group member's attendance spreadsheet available at I:\Communications\Working Group Members Meetings Attendance. The editor is requested to return the document within 4-6 weeks. On return from the medical editor the checklist is updated, and the edited changes made by the lead scientist within 40 days of return. The Head of the Standards Unit will perform the final proofread before the document is issued.

In the absence of an editor or if there is a large back log of documents the Chair of the Steering Committee or the Head of the Standards Unit may edit the

documents.

Head of Standards Unit to authorise

The Head of the Standards Unit will check the editor corrections against the document that is about to be issued along with the associated RUC and reference assessment form (the reference assessment form should be viewed electronically).

Note: The final ‘sign off’ of the development checklist by the Unit Head/senior staff demonstrates that the process has been correctly completed and that all staff involved in that document are competent in their roles.

PUBLISHED

The final draft version of the UK SMI is saved and renamed with the document number and the final draft version moved into the archive subfolder.

The footer is amended to include the issue number and issue date.

The correct document control number and date are added to the amendment table.

The UK SMI and RUCs are saved in the agreed format for the website.

The document is then uploaded to the website via the Whitehall publisher (content management system).

Details of newly issued and reissued UK SMIs are sent to the UK SMI mailing list via Gov.delivery.

If there is a delay in the reissue which is outside of the SU’s control eg medical editor vacancy or corporate Digital dept delay then the timeframe may be extended but this should be noted in the checklist database.

Quality System

The reference assessment, grading spreadsheet and endnote database should be checked and saved on Q-pulse. All information relevant to the UK SMI development should be stored electronically with no hardcopies required.

On completion of the development process the checklist should be signed. If the document in question is one that the Head of Standards Unit has worked on then an appropriate senior scientist should authorise sign off of the UK SMI contents

and associated documents. The issued document is saved indefinitely to Q-pulse and ESL archive drive and Q-pulse. A previous version (if any) will be archived. Details of and rationale for point changes and the date they were uploaded should be recorded in the Quality System (S9304). This information should be sent to the Technical Support Officer. The working folders for the process of this review are moved to the archive folder and any emails related to the document should be saved in the folder under 'Correspondence' with clear headings.

Any previously published but archived document can be made available if laboratories request them, but a watermark 'For Information' should be placed on the document indicating that the method is no longer in use and is superseded.

Implementation and marketing

The Standards Unit publish a support tool to aid implementation of UK SMIs in the form of a Standards Unit Information Leaflet (SW3074). It is produced to help users understand UK SMIs and raise awareness by distributing the leaflet at conferences and seminars. The leaflet is reviewed regularly in line with all Standard Unit internal SOPs and guidance documents and is available on the public website.

SECTION 12.0 **SUMMARY OF REVISIONS**

Full review and minor amendments made to the process. Flowchart under section 7 - Summary of the main stages of development and flowchart used for Kanban was removed as it is not adding any value. Addition of section for implementation and marketing to explain the role of the SU Information leaflet.

SECTION 13.0 **AUTHORISATION**

AUTHOR

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