The Laboratory Services Reform Programme

Process for Preparation and Dissemination of Guidance and Advice from the Laboratory Services Reform Project

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Version	Revision Date	List Section Numbers Changed	Author

1 Purpose

This document is prepared to describe the procedure followed by the Laboratory Services Reform Programme (LSRP), incorporating the National Clinical Pathology Programme (NCPP) when developing approving and disseminating Guidelines or Advice for Clinical Laboratories and their users.

2 Identification of Need

Proposals for development of advice or guidance notes may be made by any member of the LSRP team or the Clinical and Scientific Advisory Group (CSAG).

The impetus to prepare Guidance or Advice Notes can also arise from:

- Suggestions from laboratory staff
- Programme Priorities
- Requests from, or collaboration with, HSE Clinical Programmes
- Request from service users or stakeholders
- International practice notices
- Legislation
- Quality Improvement or response to identified risk

The attached advice note request may be completed to indicate the reason for an advice note and the issue of concern to be addressed

3 Document Initiation

The LSRP Clinical Lead and Programme Team agree the requirement for, and the capacity of, the programme to prepare Guidance / Advice.

The person who leads on the initial draft will normally be the principal author. An editorial group may be formed to bring the document to draft stage. In that case, each contributor will be recognised as an author. The initial draft will often be prepared by a member of the LSRP team (author) including Scientific Lead, Programme Manager or Clinical Advisor, but any member of CSAG may contribute as an author.

The objective is short practical advice to support routine laboratory practice. The draft document will be as concise as practicable. As appropriate, a reference to one or more comprehensive reviews can be included.

The document should provide the following

- Guidance / Advice for Laboratory Users
- Guidance / Advice for Laboratories
- Background information
- References

The draft is circulated for to review by the Clinical Lead, Scientific Lead, Programme Manager and Clinical Advisors and comments or suggestions are provided to the author for consideration.

After this process the Clinical Lead approves a draft document for consultation.

3.1 Stakeholder Consultation

Key Stakeholder Consultation

Where a proposed document is identified as raising particularly complex or challenging issues, has major identifiable resource requirements or potential significant implications for HSE policies the

document the Clinical Lead will discuss the proposal with the CCO in advance of consultation on a draft document.

Such draft documents will be circulated for consultation to CSAG and to identified key stakeholders, with a specified time frame for receipt of comments (normally not less than two weeks). Unless specifically stated documents sent for consultation to members of CSAG are not considered confidential, as discussion with colleagues may be valuable

Where a document is identified as raising particularly complex or challenging issues by the LSRP team or by a number of members of the CSAG, the document will be normally be tabled for discussion at a meeting of CSAG before proceeding to general consultation.

Feedback will be reviewed considered and addressed.

The updated draft will then proceed to general consultation

General Consultation

Most draft documents will proceed directly to CSAG and to general consultation at the same time.

For general consultation draft documents will be sent as appropriate to stakeholders such as (but not limited to)

- Laboratory Managers and Clinical Directors
- CSAG
- Faculty of Pathology
- Academy of Clinical Science and Laboratory Medicine
- Association of Clinical Biochemists
- Irish Clinical Scientists Association
- Clinical Leads for HSE Clinical Programmes as required
- Other specifically identified stakeholders
- Relevant Clinical Leads for HSE Clinical Programmes

Documents disseminated for general consultant are not confidential and should be discussed as widely as possible. Where possible and relevant this includes discussion with laboratory users and patients.

The period of consultation will be between 2 weeks and 1 month, depending on issue complexity and time of year.

3.2 Consideration of evidence and experience.

The process outlined capitalises in a pragmatic way on the expertise of laboratory medicine practitioners in Ireland, including the sum of their knowledge of the relevant published literature, to expedite development of practical advice and guidance. Systematic literature review is generally not practical or required. List of references will generally be limited to critically relevant documents.

4 Document Approval

Following advice and consultation with the Stakeholders the document will be edited by the Author(s) and submitted for approval.

The document will be approved, on behalf of LSRP by the Clinical Lead and thereafter in accordance with the CDI Document Approval Hierarchy of Compliance.

5 Document Publication

Documents are allocated a unique ID
Documents are published on the HSE website

Pathology - HSE.ie

5.1 Document Dissemination

Once published, notification of publication will be cascaded through HSE pathways and disseminated through professional groups. This will include those listed below.

- Clinical Directors of Pathology and Laboratory Managers
- Clinical Programmes, as appropriate
- All members of CSAG
- Faculty of Pathology
- Clinical Pathology Societies
- Academy of Clinical Science and Laboratory Medicine
- Association of Clinical Biochemists
- Irish Association of Clinical Scientists

Developed by the Laboratory Services Reform Programme Incorporating The National Clinical Pathology Programme.

Approved By: Martin Cormican MCRN 011105,
HSE Clinical Lead for Laboratory Services Reform Programme.

Request for Advice Note Preparation by Laboratory Service Reform Programme	
Requested By:	
Role	
Email:	
Reason for Request	
Issue of Concern	
Suggested Advice	
Stakeholders (please list with contact details**)**	
Date:	