

Society of Nuclear Medicine Guideline for Guideline Development

version 3.0, approved June 23, 2001

Authors: Henry D. Royal, MD-Chair (Mallinckrodt Institute of Radiology, St. Louis, MO); Helena R. Balon, MD; William Beaumont Hospital, Royal Oak, MI); Jeffrey A. Dobkin, MD (Long Beach Memorial Medical Center, Long Beach, CA); Kevin Donohoe, MD (Beth Israel Deaconess Medical Center, Boston, MA); Mickey Clarke, CNMT (Mallinckrodt Institute of Radiology, St. Louis, MO); Jaap Kuyvenhoven, MD (UMC Utrecht, Netherlands); and Mark Wittry, MD (St. Louis University, St. Louis, MO).

I. Purpose

The purpose of this guideline is to describe an explicit, well-documented methodology for the development of procedure guidelines in the field of nuclear medicine. The process necessary for Society of Nuclear Medicine approval of a procedure guideline is also described.

II. Background Information and Definitions

- A. **Procedure guidelines** summarize scientific evidence and expert opinion regarding the performance of nuclear medicine procedures. In instances where there is little scientific evidence upon which to base procedure guidelines, expert opinion will be used in conjunction with available scientific data. The intent of a procedure guideline is to describe a procedure that will maximize the diagnostic information obtained, while minimizing the resources expended. Procedure guidelines are not intended to describe "cutting edge" or "state-of-the-art" procedures that may be under development at academic medical centers, nor are they intended to be advocacy statements. Procedure guidelines are also not intended to describe the minimally-acceptable procedure.
- B. **Practice guidelines** describe the desired diagnostic and therapeutic approach to patients with specific clinical problems such as "chest pain." Practice guidelines are developed using a multidisciplinary panel of experts. Typically, the resources required to develop a practice guideline are much greater than those necessary to develop a procedure guideline.
- C. The **Guidelines and Communications Committee** consists of approximately fifteen members from both academic and nonacademic practice settings. This committee provides oversight for the development and revision of guidelines. The Chair of the Guidelines and Communications Committee will appoint a Chair for each Guideline Task Force.

- D. The **Guideline Task Force** is a committee of four to five subject experts who will review procedure guidelines for content during the development and revision processes. The Task Force chair will appoint members to the Task Force. Whenever possible, an international SNM member will be included as a member of the Guideline Task Force.
- E. The **Guideline Development Subcommittee** is a group of four to five methodologists who will review procedure guidelines for format and style during the development and (if needed) revision processes.

III. Methodology

- A. Relevant guidelines from other organizations will be reviewed and taken into consideration. Literature searches will be performed to include current scientific evidence. The guideline task force members will be explicitly identified in an appendix to the guideline and each step of the development of the guideline will be documented.
- B. Procedure guidelines will not have the same instrument-specific details as a procedure manual. Site-specific procedure manuals can only be developed by nuclear medicine practitioners at each site. Procedure guidelines are one of several sources of information that are useful when nuclear medicine practitioners write their own site-specific procedure manual.
- C. Guidelines should include only references to radiopharmaceuticals and drugs that have been approved for routine use. Generic names should be used rather than trade names. For consistency with the editorial policy of *The Journal of Nuclear Medicine*, SI units will be used with non-SI units in parentheses.
- D. It is expected that guidelines will undergo numerous detailed reviews and revisions by the Task Force members and by members of the Guideline Development Subcommittee. These re-

viewers will indicate on a line-by-line basis any suggestions or recommendations for the revision of the guideline. The percentage of agreement for each reviewer and an average percentage of agreement for all reviewers will be calculated for each revision and compiled by SNM central office. It is expected that the percentage of agreement will increase with each revision.

- E. Reviewers' comments will be compiled into a report providing the commenter's name, the line number to which the comment refers (sorted sequentially), and the comment itself. This report will be used for subsequent revisions of the guideline. The action taken by the Task Force Chair in response to each comment [Fully Implemented (I); Partially Implemented (P); Not Implemented (N)] will be recorded. When available, the reason for not implementing a comment (N) will be noted.
- F. When the Task Force and Guideline Development Subcommittee have completed their edits, draft procedure guidelines will be distributed to the SNM Sample Review Group for comment. (The SNM Sample Review Group is a cross-section of approximately 100 nuclear medicine practitioners representing every field of specialization). These reviewers need not comment on a line-by-line basis but will complete a brief survey, and will be allowed to provide specific comments on the survey form.
- G. Each new draft of the guideline will be titled draft 0.0, 0.1, 0.2, etc. The first SNM-approved version of the guideline will be titled Version 1.0.
- H. Procedure Guidelines must be reviewed and revised as appropriate, approximately every 3 to 4 years. All Task Force members will be sent the most recent version of their guideline, a line-by-line comment form, and the most recent version of the Guideline for Guideline Development for reference. They will be asked to provide comments and/or revisions, as necessary. New technologies or radiopharmaceuticals must be noted. A new literature search must be performed to obtain the most current scientific evidence available on the procedure. Comments must be received from the Task Force Chair (the primary author) and at least two other members of the Task Force. Those comments will be compiled into a report at the SNM central office.

The Comments Report will be sent to the Task Force Chair, with a copy sent to the Guidelines and Communications Committee Chair. The Task Force Chair will be asked to review the report and decide which comments should be fully implemented, partially implemented, or not implemented. The Task Force Chair will also be

asked to determine whether the revisions are substantial enough to warrant further reviews by either the Task Force, the Guideline Development Subcommittee, or the SNM Sample Review Group. When all reviewers are satisfied with the new version of the guideline, it will be distributed to the House of Delegates and voted on for re-approval at the Mid-Winter or Annual Meeting.

- I. The chair of each taskforce determines the authorship of each guideline prior to its approval by the House of Delegates. In general, each contributing member of the taskforce for the guideline will be considered an author. In addition, other authors may be added at the discretion of the chair. The authors of the current guideline will be listed following the title of the guideline. The chair of the taskforce is listed as first author. The authors of prior guidelines will be listed following the date of approval for each version of the guidelines in section IX C.
- J. At the Mid-Winter and Annual Meetings, new or revised procedure guidelines will be reviewed and approved by the Guidelines and Communications Committee in a reference hearing open to SNM members. The guidelines will then be forwarded to the House of Delegates for their approval. Approval of a guideline requires a simple majority of the members of each group. These approvals can be obtained in writing if it is necessary to approve a guideline between meetings.
- K. Society members will be notified about the approval of procedure guidelines by publishing either an announcement or the actual document in *The Journal of Nuclear Medicine*.
- L. The appendix, entitled "Description of Guideline Development Process," will not be routinely disseminated, but will be available upon request.

IV. Format of Guidelines

Most procedure guidelines should be written using a uniform format. The suggested format is:

- I. Purpose
- II. Background Information and Definitions
- III. Common Indications
- IV. Procedure
 - A. Patient Preparation
 - B. Information Pertinent to Performing the Procedure

This section should list the important data that the physician should have about the patient at the time the exam is performed and interpreted. This data should include the results of a history and physical examination performed

by the nuclear medicine physician.

C. Precautions

Common, important, widely accepted procedure specific precautions should be listed in this section. Precautions that commonly apply to many nuclear medicine procedures should be listed in the Guideline for General Imaging. The purpose of listing precautions is to alert nuclear medicine practitioners about actions or omissions that have the potential for causing the patient significant harm.

D. Radiopharmaceutical

Ranges of administered activity are preferred. The term "administered activity" should be used rather than "dose." All guidelines should include a table of dosimetry. (When indicated, a dosimetry table for children should be included.) The values for this table are usually readily available from the Society of Nuclear Medicine MIRD committee, ICRP 53 and ICRP 62. The source for these values should be referenced. The table should consist of four columns. An example from the thyroid imaging guideline is given below.

E. Image Acquisition

F. Interventions

G. Processing

H. Interpretation Criteria

In this section, the Interpretation

Criteria should be summarized for the procedure. An effort should be made to distinguish criteria that are widely used and well validated from criteria that are less reliable.

I. Reporting

A generic report template will be provided in the Procedure Guideline for General Imaging. The reporting section of all other guidelines will be used to describe items specific to that procedure that should be included in the report.

J. Quality Control

K. Sources of Error

V. Issues Requiring Further Clarification

VI. Concise Bibliography

VII. Disclaimer

The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in

Radiation Dosimetry in Adults

Radiopharmaceuticals	Administered Activity MBq (mCi)	Organ Receiving the Largest Radiation Dose mGy per MBq (rad per mCi)	Effective Dose mSv per MBq (rem per mCi)
<i>I-131 iodide</i> ¹	1.85 – 7.4 p.o. (0.05 – 0.2)	210 Thyroid (780)	6.6 (24.0)
<i>I-123 iodide</i> ²	7.5 – 25 p.o. (0.2 – 0.6)	1.9 Thyroid (7.0)	0.075 (0.28)
<i>Tc-99m pertechnetate</i> ³	75 – 370 i.v. (2 – 10)	0.062 ULI ⁴ (0.23)	0.013 (0.048)

¹ICRP 53, page 276, assuming 15% uptake

²ICRP 53, page 264, assuming 15% uptake

³ICRP 53, page 199, no blocking agent

⁴Upper Large Intestine

**Radiation Dosimetry in Children
(5 year old)**

Radiopharmaceuticals	Administered Activity MBq (mCi)	Organ Receiving the Largest Radiation Dose mGy (rad per mCi)	Effective Dose* mSv (rem per mCi)
<i>I-131 iodide¹</i>	<i>0.025 – 0.1 p.o. (0.0004 – 0.0016)</i>	<i>1,100 Thyroid (4,100)</i>	<i>34 (130)</i>
<i>I-123 iodide²</i>	<i>0.1 – 0.3 p.o. (0.003 – 0.01)</i>	<i>9.8 Thyroid (36)</i>	<i>0.35 (1.3)</i>
<i>Tc-99m pertechnetate³</i>	<i>75 – 370 i.v. (2 – 10)</i>	<i>0.062 ULI⁴ (0.23)</i>	<i>0.013 (0.048)</i>

¹ICRP 53, page 276, assuming 15% uptake

²ICRP 53, page 264, assuming 15% uptake

³ICRP 53, page 199, no blocking agent

⁴Upper Large Intestine

part on the prevalence of disease in the patient population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.

Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.

VIII. Last House of Delegates Approval Date:
mm/dd/yy

IX. Next Anticipated Approval Date:
mm/dd/yy

X. Appendix: Description of Guideline Development Process

A. Guideline Development Subcommittee
List of four to five names from the subcommittee who are currently assigned to comment on format and style of the guideline on a line-by-line basis.

B. Task Force Members
List of four to five names from the subject experts who are currently assigned to comment on the content of the guideline on a line-by-line basis. The Chair of each task force should be noted as such.

C. History of House of Delegates Approval Dates

D. Revision History

1. Draft 0.0-Initial authors of the

guideline or source organization

a. Names of each detailed reviewer are listed with the percentage of lines with which the reviewer agreed.

b. Names of other reviewers are listed.

c. Line-by-line listing of all comments and the action taken on each comment [Fully Implemented (I); Partially Implemented (P); or Not Implemented (N)].

d. Date completed: mm/dd/yy

2. Draft 0.1

a. Names of each detailed reviewer are listed with the percentage of lines with which the reviewer agreed.

b. Names of other reviewers are listed.

c. Line-by-line listing of all comments and the action taken on each comment [Fully Implemented (I); Partially Implemented (P); or Not Implemented (N)].

d. Date completed: mm/dd/yy

3. Draft 0.2

a. Names of each detailed reviewer are listed with the percentage of lines with which

- the reviewer agreed.*
 - b. Names of other reviewers are listed.
 - c. Line-by-line listing of all comments and the action taken on each comment [Fully Implemented (I); Partially Implemented (P); or Not Implemented (N)].
 - d. Date completed: mm/dd/yy
4. Draft 0.3
- a. Names of each detailed reviewer are listed with the percentage of lines with which the reviewer agreed.
 - b. Names of other reviewers are listed.
 - c. Line-by-line listing of all comments and the action taken on each comment [Fully Implemented (I); Partially Implemented (P); or Not Implemented (N)].
 - d. Date completed: mm/dd/yy

V. Issues Requiring Further Clarification

None

VI. Concise Bibliography

The following references deal primarily with the development of practice guidelines. Many of the general concepts have been used in the SNM procedure guideline development process.

Eddy DM. The explicit approach. In: *A Manual for Assessing Health Care Practices and Designing Practice Policies*. Philadelphia, PA: American College of Physicians; 1992.

A step-by-step guide of the guideline development process.

Gundersen L. The effect of clinical practice guidelines on variations in care. *Ann Intern Med*. 2000;133:317–318. The author comments about the effect of guidelines on clinical practice.

Hyams AL, Brandenburg JA, Lipsitz SR, et al. Practice guidelines and malpractice litigation: a two-way street. *Ann Intern Med*. 1995;122:450–455.

The authors reviewed insurance claims and surveyed attorneys to determine the effects of guidelines on malpractice litigation.

Lohr KN, Eleazer K, et al. *Health Policy Issues and Applications for Evidence-Based Medicine and Clinical Practice Guidelines*. Health Policy. 1998;46:1–19.

A brief overview of evidence-based medicine and clin-

ical practice guidelines and how they are likely to influence health policy.

McDonald CJ, Overhage TM. Guidelines you can follow and trust: An ideal and an example. *JAMA*. 1994;271:872–873.

Editorial prompted by concurrent publication of a guideline describing the “rules” for deciding if ankle radiographs are necessary.

Woolf SH. *Interim Manual for Clinical Practice Guideline Development*. Public Health Service, Agency for Health Care Policy and Research, Washington, DC: AHCPR Publication. 1991;91-0018.

A step-by-step manual for the guideline development process.

Woolf SH. Practice guidelines, a new reality in medicine: I. Recent developments. *Arch Intern Med*. 1990;150:1811–1818.

A three-part introduction to practice guidelines. The author has served as a consultant to the SNM.

Woolf SH. Practice guidelines, a new reality in medicine: II. Methods of developing guidelines. *Arch Intern Med*. 1992;152:946–952.

See above.

Woolf SH. Practice guidelines, a new reality in medicine: III. Impact on patient care. *Arch Intern Med*. 1993;153:2646–2655.

See above.

Evidence-Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA*. 1992; 268:2420–2425.

A thoughtful introduction to what is meant by evidence-based medicine.

VIII. Disclaimer

The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.

Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.