

Guidelines for Guideline Development

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PART 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. This guideline is intended to aid nuclear medicine practitioners in the development of procedure guidelines within the specialty of nuclear medicine. These procedure guidelines should become part of practice guidelines that are subsequently developed in conjunction with primary care physicians and other specialists. The process necessary for Society of Nuclear Medicine endorsement of a procedure guideline is also described.

PART II: BACKGROUND INFORMATION AND DEFINITIONS

Procedure guidelines will be developed predominately within the Society of Nuclear Medicine. The purpose of procedure guidelines is to summarize scientific evidence and expert opinion about the performance of nuclear medicine procedures. Because there is little scientific evidence upon which to base procedure guidelines, expert opinion must often be used in conjunction with available scientific data. The intent of a procedure guideline is to describe a procedure which will maximize the diagnostic information obtained in a study while minimizing the resources that are 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.

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.

Guideline Development Subcommittee is a subcommittee of the Technology and Outcomes Assessment Committee and the Guidelines and Communications Committee. This subcommittee should consist of approximately 15 members from both academic and nonacademic practice settings. Approximately one-half of the committee members should be appointed by the Technology and Outcomes Assessment Committee, while the other one-half should be appointed by the Guidelines and Communications Committee.

Expert Task Force is a committee of four to five subject experts who will review procedure guidelines in detail during the development process.

PART III: METHODOLOGY

- A. Due to the urgency for developing guidelines, the initial set of procedure guidelines will be primarily based on expert opinion. Relevant guidelines from other organizations should be reviewed. The experts will be explicitly identified in an appendix to the guideline and the steps in the guideline development will be documented. The long-term goal is to develop evidence-based guidelines when possible.
- B. Procedure guidelines will not have the same instrument-specific details as a procedure manual. Site-specific procedure manuals can only be developed by local physicians.
- 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 the initial guidelines will undergo four detailed reviews and revisions by four to five subject experts (Task Force members) and by four to five methodologists (members of Guideline Development Subcommittee). These reviewers will indicate on a line-by-line basis whether they agree with the guideline. The percent agreement for each reviewer and a total percent agreement for each revision will be calculated. It is expected that the percent agreement will increase with each revision.
- E. Draft procedure guidelines will be sent to many interested reviewers by the Guidelines and Communications Committee. These reviewers need not comment on a line-by-line basis, but their comments will be tabulated as described below.
- F. The reviewer that made the comment, the line number of the document that prompted the comment and the comment will all be recorded in a table that will be sorted by line number. This table will be used for subsequent revisions of the guideline. The action taken in response to each comment [Fully Implemented (I); Partially Implemented (P); Not Implemented (N)] will be recorded.
- G. Draft versions of procedure guidelines will be widely distributed for comment from Society of Nuclear Medicine members prior to their approval. This activity will be the responsibility of the Guidelines and Communications Committee.
- H. The draft documents will be numbered draft 0.0, draft 0.1, etc. The first SNM endorsed version will be called Version 1.0.
- I. Procedure guidelines should be regarded as living documents that will be reviewed and revised as appropriate, approximately every 2 yr.
- J. Procedure guidelines must be approved by the Guideline Development Subcommittee prior to being forwarded to the steering committee of the Commission on Health Care Policy. If approved by the Commission, the guideline will

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be forwarded to the Board of Directors and then 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.

- K. Society members will be notified about the approval of procedure guidelines by publishing an announcement or the actual document in *The Journal of Nuclear Medicine*.
- L. A follow-up survey will be conducted at (annual) intervals, under the leadership of the Chair of the Guidelines and Communications Committee with the assistance of the staff of the Commission on Health Care Policy, to ascertain the "outcome" of the approval and publication of procedure guidelines.
- M. The appendix entitled "Description of Guideline Development Process" will not be routinely disseminated, but it will be available upon request.

PART IV: FORMAT OF GUIDELINES

- A. Procedure guidelines should be procedure-specific and should include common indications for that procedure.
- B. Most procedure guidelines can 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
 - D. Radiopharmaceutical

Ranges of administered activity are preferred. The term "administered activity" should be used rather than the term injected dose. All guidelines should include a table of dosimetry. 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.

Radiation Dosimetry in Adults

Radiopharmaceuticals	Administered activity MBq (mCi)	Organ receiving the largest radiation dose mGy* (rad) [†]	Effective dose mSv* (rem) [†]
[¹³¹ I]iodide [‡]	1.85–7.4 p.o. (0.05–0.2)	210 Thyroid (780)	6.6 (24.4)
[¹²³ I]iodide [§]	7.5–25 p.o. (0.2–0.6)	1.9 Thyroid (7.0)	0.075 (0.278)
[^{99m} Tc]pertechnetate	75–370 i.v. (2–10)	0.062 ULI** (0.23)	0.013 (0.048)

*per MBq.

[†]per mCi.

[‡]ICRP 53, p. 276, assuming 15% uptake.

[§]ICRP 53, p. 264, assuming 15% uptake.

^{||}ICRP 53, p. 199, no blocking agent.

**ULI = upper large intestine.

Radiation Dosimetry in Children
(5 Year Old)

Radiopharmaceuticals	Administered activity MBq/kg (mCi/kg)	Organ receiving the largest radiation dose mGy* (rad) [†]	Effective dose mSv* (rem) [†]
[¹³¹ I]iodide [‡]	0.025–0.1 p.o. (0.0004–0.0016)	1,100 thyroid (4,070)	34 (40.7)
[¹²³ I]iodide [§]	0.1–0.3 p.o. (0.003–0.01)	9.8 thyroid (36.3)	0.35 (1.3)
[^{99m} Tc]pertechnetate	1–5 i.v. (0.015–0.07)	0.21 ULI (0.78)	0.04 (0.15)

*per MBq.

[†]per mCi.

[‡]ICRP 53, p. 276, assuming 15% uptake.

[§]ICRP 53, p. 264, assuming 15% uptake.

^{||}ICRP 53, p. 199, no blocking agent.

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- E. Image Acquisition
- F. Interventions
- G. Processing
- H. Interpretation/Reporting
- I. Quality Control
- J. Sources of Error

V. Disclaimer

The Society of Nuclear Medicine has developed guidelines to promote the cost-effective use of 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.

VI. Issues Requiring Further Clarification

VII. Concise Bibliography

An annotated concise bibliography of 10 or less references will be cited. A more comprehensive bibliography of recent (less than 5 yr old) will be encouraged in the next version of the procedure guidelines.

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 subsequent revisions 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 subse-

quent revisions of the guideline on a line-by-line basis.

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 (8–10) is 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 (No action; Partial implementation; Done).
 - d. Date completed: mm/dd/yy
2. Draft 0.1
 - a. Name of each detailed reviewer (8–10) is 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 (No action; Partial implementation; Done).
 - d. Date completed: mm/dd/yy
3. Draft 0.2
 - a. Name of each detailed reviewer (8–10) is 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 (No action; Partial implementation; Done).
 - d. Date completed: mm/dd/yy
4. Draft 0.3
 - a. Name of each detailed reviewer (8–10) is 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 (No action; Partial implementation; Done).
 - d. Date completed: mm/dd/yy

PART V: DISCLAIMER

The Society of Nuclear Medicine has developed guidelines to promote the cost-effective use of 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.

VI. ISSUES REQUIRING FURTHER CLARIFICATION

None

VII. 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.

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10. Woolf SH. Practice guidelines, a new reality in medicine: II. Methods of developing guidelines. *Arch Intern Med* 1992;152:946–952. See above.
11. Woolf SH. Practice guidelines, a new reality in medicine: III. Impact on patient care. *Arch Intern Med* 1993;153:2646–2655. See above.

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

PART VIII: LAST BOARD OF TRUSTEES APPROVAL DATE

February 12, 1995

PART IX: NEXT ANTICIPATED APPROVAL DATE

1997.

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Procedure Guideline for Bone Pain Treatment: 1.0

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Key Words: strontium-89 therapy; osseous metastasis; practice guideline

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PART I: PURPOSE

The purpose of this guideline is to assist nuclear medicine practitioners in evaluating patients who might be candidates for Strontium-89 (^{89}Sr) treatment of bone pain due to osteoblastic metastases, to provide information for performing this treatment and to assist in understanding the sequelae of therapy.

PART II: BACKGROUND INFORMATION AND DEFINITIONS

A. Definitions

1. Strontium-89 therapy means the intravenous injection of the radionuclide ^{89}Sr as the soluble salt strontium chloride. Strontium-89 emits a beta particle with maximum energy 1.463 MeV, mean energy 0.58 MeV, average soft-tissue range 2.4 mm and a 0.01% abundant gamma emission with a photopeak of 0.910 MeV. It has a 50.5 day physical half-life.
2. "Osteoblastic" or "osteoblastic metastases" mean foci of increased activity on bone scintigraphy caused by osseous reaction to tumor in bone.

B. Background

Intravenous injection of ^{89}Sr -chloride has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of bone pain due to osteoblastic metastasis. Physicians involved in treating such patients should have an understanding of the natural history of the disease process and should be able to collaborate closely with the physician or group of physicians handling the overall management of the patient's disease.

The administration of this agent falls under the guidelines of the Nuclear Regulatory Commission (NRC), Title 10 CFR Part 35.300 or Agreement State Institutional License. Institutional licenses must specif-

ically list individuals licensed to use Section 35.300 materials.

As other radiopharmaceuticals are approved by the FDA for the treatment of bone pain due to osteoblastic metastases, they will be added to the guideline.

PART III: COMMON INDICATIONS

Strontium-89-chloride (and the other unsealed beta- or conversion electron-emitting radiopharmaceuticals under development or available commercially, i.e. ^{32}P -orthophosphate) is indicated for the treatment of bone pain due to a metastatic malignancy that has involved multiple skeletal sites and has evoked an osteoblastic response on bone scintigraphy. Where there is danger of either spinal cord compression from vertebral metastases or pathologic fracture in the extremities, ^{89}Sr therapy should only be used in conjunction with other forms of management directed at these complications.

PART IV: PROCEDURE

A. Facility/Personnel

1. Strontium-89 may only be administered in a facility with a valid radioactive materials license incorporating Section 35.300 or comparable Agreement State License.
2. All administering physicians (the physician writing the prescription and injecting the dose) must be listed on the NRC or Agreement State license or specifically designated under a broad license.
3. Patients should be seen in consultation by the administering/treating physician in collaboration with the physician assuming overall patient management.
4. The administering physician should be board certified in nuclear medicine, radiology, radiation oncology or be able to document equivalent training, competency and experience in the safe use and administration of unsealed radiotherapeutic sources.
5. The administering physician should participate in the ongoing and follow-up care of the patient as part of the patient management team.
6. The facility in which the treatment is performed must have proper radiation safety procedures, in-

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