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SNM/EANM Guideline for Guideline Development 6.0*

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PREAMBLE

The Society of Nuclear Medicine (SNM) is an international scientific and professional organization founded in 1954 to promote the science, technology, and practical application of nuclear medicine. The European Association of Nuclear Medicine (EANM) is a professional nonprofit medical association that facilitates communication worldwide between individuals pursuing clinical and research excellence in nuclear medicine. The EANM was founded in 1985. SNM and EANM members are physicians, technologists, and scientists specializing in the research and practice of nuclear medicine.

The SNM and EANM will periodically define new guidelines for nuclear medicine practice to help advance the science of nuclear medicine and to improve the quality of service to patients throughout the world. Existing practice guidelines will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline, representing a policy statement by the SNM/EANM, has undergone a thorough consensus process in which it has been subjected to extensive review. The SNM and EANM recognize that the safe and effective use of diagnostic nuclear medicine imaging requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline by those entities not providing these services is not authorized.

These guidelines are an educational tool designed to assist practitioners in providing appropriate care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, both the SNM and the EANM caution against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, there is no implication that an approach differing from the guidelines, standing alone, is below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines.

The practice of medicine includes both the art and the science of the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not ensure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

The purpose of this guideline is to describe an explicit, well-documented methodology for the development of guidelines in the field of nuclear medicine. The process necessary for approval of a guideline is also described. The same process is applicable for approval of SNM- or EANM-only guidelines and collaborative guidelines. For SNM-only guidelines, the EANM committees and executive committee do not need to review and approve the guideline. For EANM-only guidelines, the SNM committees and SNM Board of Directors do not need to review and approve the guideline.

II. GOALS

The goal of the 2012 update is to revise the format and process of the SNM guideline to include collaborative

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*NOTE: YOU CAN ACCESS THIS GUIDELINE THROUGH THE SNM WEB SITE (http://www.snm.org/guidelines).
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guidelines with EANM. The long-term goal is to have guidelines that are revised and endorsed by multiple organizations.

III. DEFINITIONS

The SNM Committee on Guidelines consists of approximately 15 members from both academic and nonacademic practice settings. This committee provides oversight for the development and revision of guidelines. The chair of the SNM Committee on Guidelines will appoint a chair for each guideline writing group.

The EANM Executive Committee, through the task group and committee coordinator, approves the proposal of guidelines coming from the committees and asks the committees to write or review guidelines.

The guideline writing group is a committee of experts appointed by the chair of the writing group. The guideline writing group reviews guidelines for content during the development and revision processes. For SNM guidelines, an international SNM member, a young professional, a SNM technologist member, and a SNM representative to collaborative guidelines with other organizations, such as the EANM or the American College of Radiology, will be included whenever possible as a member of the guideline writing group. For collaborative guidelines, members of the writing groups will be appointed by the chair and vice-chair.

The SNM councils are groups of experts and will be consulted as appropriate to recommend members for guideline writing groups and to review drafts of guidelines.

The EANM committees are groups of experts equivalent to the SNM councils. The EANM committees are coordinated by the EANM committee coordinator, who is a member of the EANM Executive Committee. Members of the appropriate EANM committees will participate in the writing and review of guidelines.

The SNM/EANM Guideline Steering Committee was formed in January 2012. This committee has 2 cochairs, one from the SNM and one from the EANM. The SNM/EANM Guideline Steering Committee also has 3 additional members from each organization, with the chair of the SNM Committee on Guidelines being one of the SNM appointees. The cochairs and committee members are appointed by the SNM and the EANM Executive Committee for a term of 1 y, renewable. The charge of this committee is to define the process and format of SNM/EANM collaborative guidelines, identify new guidelines of interest for collaboration, and appoint the chair and vice-chair of the writing group for SNM/EANM collaborative guidelines. Staff of SNM and EANM will alternate responsibility for administrative support.

Guidelines will be published in *The Journal of Nuclear Medicine, European Journal of Nuclear Medicine and Molecular Imaging,* or *Journal of Nuclear Medicine Technology* as appropriate and agreed on between the editors.

Guidelines will not have the same instrument-specific details as a procedure manual. Site-specific procedure manuals can be developed only by nuclear medicine practitioners at each site. Guidelines are one of several sources of information that are useful when nuclear medicine practitioners write their own site-specific procedure manual.

To maintain the highest-quality standards and the scientific integrity of guidelines, the SNM and EANM have adopted specific conflict-of-interest screening criteria that must be respected when a guideline is written. Conflict-of-interest documents are available on the respective Web sites. When other scientific societies participate in the guideline writing process, their conflict-of-interest policies must also be considered.

IV. METHODOLOGY

A. Radiopharmaceuticals

Guidelines should include references to only radiopharmaceuticals and drugs that have been approved for routine use in the Americas or Europe. Generic names should be used rather than trade names. When a particular radiopharmaceutical is approved in only one country, this should be acknowledged in the guideline. If there are different diagnostic accuracies between the different radiopharmaceuticals listed in a guideline, those differences should be discussed in the guideline.

B. Review of the literature

Relevant guidelines and appropriate-use criteria from other organizations will be reviewed. Literature searches will be performed to include current scientific evidence. The search terms used to review the literature should be documented, as well as the criteria for including the discovered articles in the development of the guideline.

C. First draft of the guideline by the writing group

The chair of the writing group will write the first draft in the format recommended in section V below. This draft will be reviewed and revised by the writing group and finalized by the chair.

D. Review by SNM councils, EANM committees, and SNM Committee on Guidelines

The chair of the writing group and the chair of the SNM Committee on Guidelines will identify the appropriate SNM councils and EANM committees to review the guideline after approval by the writing group. The guideline will be reviewed by the SNM councils, EANM committees, and the SNM Committee on Guidelines. These reviewers will indicate on a line-by-line basis any suggestions or recommendations for the revision of the guideline.

E. Comments report and semifinal draft

The reviewers' comments will be compiled by SNM or EANM staff into a report listing the commenter's name, the line number to which the comment refers (sorted sequentially), and the comment itself. The comments report will be sent to the chair of the writing group, with a copy sent to the chair of the SNM Committee on Guidelines and to the EANM committee coordinator. The chair of the writing group will revise the guideline according to the comments report. Individual comments may be accepted in full, accepted in part, or rejected. The chair of the writing group should include an explanatory note next to comments that are rejected. Several iterations of this process may occur before a semifinal draft is approved by the writing group and its chair. The semifinal draft is then sent to the chair of the SNM Committee on Guidelines and to the EANM Executive Committee.

F. Public comments

After approval by the chair of the SNM Committee on Guidelines and the EANM Executive Committee, the semifinal draft of the guideline will be made available through the SNM Web site to members for 2 wk of commenting. EANM will make the SNM/EANM guidelines available to national societies, as appropriate.

G. Name of sequential draft of guidelines

Each new draft of the guideline approved by the chair of the writing group will be titled draft 0.0, 0.1, 0.2, etc. The first version of the guideline given final approval by both the SNM and EANM will be titled version 1.0. Final approved revisions in subsequent years will be version 2.0, 3.0, etc.

H. Authorship

The chair of each writing group determines the authorship of each guideline before its approval by the SNM Board of Directors and EANM Executive Committee. In general, each contributing member of the writing group for the guideline will be considered an author. In addition, other authors may be added at the discretion of the chair. The chair of the writing group is listed as first author, with the vice-chair listed as second author. Other members of the writing group and additional authors indicated by the chair of the writing group will be listed in alphabetical order.

I. Final approval

New or revised (see section K) guidelines will be reviewed and approved by the SNM Committee on Guidelines. The guidelines will then be forwarded to the SNM Board of Directors and to the EANM Executive Committee for their final approval.

J. Notification to society members

The membership will be notified about the approval of guidelines through an announcement posted on the SNM and EANM Web sites, as appropriate, along with publication of the guideline or an announcement in *The Journal of Nuclear Medicine, European Journal of Nuclear Medicine and Molecular Imaging,* or *Journal of Nuclear Medicine Technology.*

K. Revision cycle

Guidelines must be reviewed and revised approximately every 5 y (or earlier if needed).

The chair of the SNM Committee on Guidelines and cochairs of the SNM/EANM Guideline Steering Committee will either reappoint the chair of the former writing group or appoint a new chair. The chair will appoint the writing group members. The number of members is at the discretion of the chair. At least 3 members, including the chair, should review the guideline and provide comments documented by the SNM or EANM guideline staff.

The revision process is the same as described in sections IV.C through IV.G, depending on the extent of revisions needed. All writing group members will be sent the most recent version of the guideline and the most recent version of this Guideline for Guideline Development for reference. They will be asked to provide comments or revisions, as necessary, with tracked changes in the document. New technologies or radiopharmaceuticals must be added. A new literature search must be performed to obtain the most current scientific evidence available on the procedure. The literature search methodology should be documented as described above for new guidelines.

The comments report will be sent to the chair of the writing group, with a copy sent to the chair of the SNM Committee on Guidelines and the EANM Executive Committee. The chair of the writing group will decide which comments should be fully implemented, partially implemented, or not implemented and determine whether the revisions are substantial enough to warrant further reviews by the writing group, the appropriate councils, the SNM Committee on Guidelines, and the EANM committees and whether the draft should be made available for public comment.

The chair of the SNM Guidelines Committee and the EANM committee coordinator will be able, at his or her discretion, to make changes to a guideline in any stage of the process, with the permission of the chair of the writing group. These changes typically are minor grammatical corrections or for purposes of standardization. If the chair considers the proposed changes to be substantial enough to require review by the writing group, the chair can decide to resend the guideline to the rest of the writing group.

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V. FORMAT OF GUIDELINES

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

PREAMBLE

The preamble of this SNM/EANM Guideline on Guideline Development can serve as an example.

I. INTRODUCTION

This section should summarize the background information about the radiopharmaceuticals used and the imaging or therapeutic procedures. Approval of radiopharmaceuticals and procedures by regulatory agencies in the United States and in Europe should be addressed, as appropriate.

II. GOALS

This section should address the goals of the guideline.

III. DEFINITIONS

Any necessary definitions should be described, or this section can be described as "not applicable."

IV. COMMON CLINICAL INDICATIONS

This section should include the introductory statement "Indications for [INSERT PROCEDURE] include, but are not limited to, the following." Reference to appropriate-use criteria should be made, as appropriate,

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

This section should describe the qualifications and responsibilities for physicians, medical physicists, and technologists and should address differences between the United States and European requirements, as appropriate.

VI. PROCEDURE/SPECIFICATIONS OF THE EXAMINATION

A. Request

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

B. Patient preparation and 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 SNM Guideline for General Imaging. The purpose of listing precautions is to alert nuclear medicine practitioners about actions or omissions that have the potential to jeopardize patient safety.

C. Radiopharmaceuticals

Ranges of administered activity are preferred. The term *administered activity* should be used rather than *dose.* Administered activity for pediatric patients should comply with the 2010 North American Consensus Guidelines (*1*) and the EANM Dosage Card, when appropriate. When the same tracer is not available in both the United States and Europe, the alternatives (if any) should be mentioned and their relative accuracy should be discussed in the appropriate sections below.

D. Protocol/image acquisition

This section should include information on interventions and processing.

E. Interpretation

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. Sources of error and issues requiring further clarification should be included.

VII. DOCUMENTATION/REPORTING

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

VIII. EQUIPMENT SPECIFICATIONS

IX. QUALITY CONTROL AND IMPROVEMENT

X. SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

XI. RADIATION SAFETY IN IMAGING

An SNM guideline on dosimetry is being developed. When approved and available, this guideline will supersede the radiation dosimetry tables in individual guidelines. Approval for each guideline should be obtained from the EANM Dosimetry Committee during the guideline writing process.

The values for the radiation dosimetry tables are usually readily available from the SNM MIRD committee, ICRP 53, and its addenda (*2–5*). The source for these values should be referenced. An example from the SNM Guideline for Lung Scintigraphy 4.0 (2011) is given in the Appendix. Radiation dosimetry tables for children and fetuses (*6*) should be included when available and appropriate. Information for breast-feeding patients should also be provided according to ICRP Publication 106, Appendix D (*3*).

XII. ACKNOWLEDGMENTS

This section should list the members of the SNM Committee on Guidelines who were in place at the time the guideline was approved, with the chair of the committee listed first. If the EANM committees were involved in the guideline writing process, the acknowledgments should list all members who contributed, as appropriate.

XIII. REFERENCES

References should be cited numerically within the document and then listed chronologically within this section in the appropriate format for *The Journal of Nuclear Medicine, European Journal of Nuclear Medicine and Molecular Imaging,* or *Journal of Nuclear Medicine Technology.* References from the tables should also be included in the reference list.

XIV. APPROVAL

The date on which the Board of Directors approved the current and previous versions of the guideline is given in this section.

XII. ACKNOWLEDGMENTS

The Committee on SNM Guidelines consists of the following individuals: Kevin J. Donohoe, MD (Chair) (Beth

Israel Deaconess Medical Center, Boston, MA); Sue Abreu, MD (Sue Abreu Consulting, Nichols Hills, OK); Helena Balon, MD (Beaumont Health System, Royal Oak, MI); Twyla Bartel, DO (UAMS, Little Rock, AR); Paul E. Christian, CNMT, BS, PET (Huntsman Cancer Institute, University of Utah, Salt Lake City, UT); Dominique Delbeke, MD (Vanderbilt University Medical Center, Nashville, TN); Vasken Dilsizian, MD (University of Maryland Medical Center, Baltimore, MD); Kent Friedman, MD (NYU School of Medicine, New York, NY); James R. Galt, PhD (Emory University Hospital, Atlanta, GA); Jay A. Harolds, MD (OUHSC–Department of Radiological Science, Edmond, OK); Aaron Jessop, MD (UT M.D. Anderson Cancer Center, Houston, TX); David H. Lewis, MD (Harborview Medical Center, Seattle, WA); J. Anthony Parker, MD, PhD (Beth Israel Deaconess Medical Center, Boston, MA); James A. Ponto, RPh, BCNP (University of Iowa Hospitals and Clinics, Iowa City, IA); Lynne T. Roy, CNMT, FSNMTS (Cedars-Sinai Medical Center, Los Angeles, CA); Heiko Schoder, MD (Memorial Sloan-Kettering Cancer Center, New York, NY); Barry L. Shulkin, MD, MBA (St. Jude Children's Research Hospital, Memphis, TN); Michael G. Stabin, PhD (Vanderbilt University, Nashville, TN); and Mark Tulchinsky, MD (Milton S. Hershey Medical Center, Hershey, PA).

The EANM Executive Committee consists of the following individuals: Emilio Bombardieri, MD (Foundation IRCCS "Instituto Nazionale Tumori," Milano, Italy); Patrick Bourguet, MD (CRLCC Centre Eugene Marquis, Rennes, France); Arturo Chiti, MD (Istituto Clinico Humanitas, Milan, Italy); Jure Fettich, MD (University Medical Center Ljubljana, Ljubljana, Slovenia); Savvas Frangos, MD (Bank of Cyprus Oncology Center, Nicosia, Cyprus); Dominique Le Guludec, MD (Hopital Bichat, Paris, France); and Johan F. Verzijlbergen, MD (Erasmus MC, Rotterdam, The Netherlands).

VII. REFERENCES

1. Gelfand MJ, Parisi M, Treves ST. Pediatric radiopharmaceutical administered doses: 2010 North American consensus guidelines. *J Nucl Med.* 2011;52:318–322.
2. International Commission on Radiological Protection. ICRP publication 53: radiation dose to patients from radiopharmaceuticals. *Ann ICRP.* 1988;18:1–4.
3. International Commission on Radiological Protection. Radiation dose to patients from radiopharmaceuticals: addendum 2 to ICRP publication 53. *Ann ICRP.* 1998;28:1–126.
4. Watson EE. Radiation absorbed dose to the human fetal thyroid. In: *Fifth International Radiopharmaceutical Dosimetry Symposium.* Oak Ridge, TN: Oak Ridge Associated Universities; 1992:179–187.
5. International Commission on Radiological Protection. ICRP publication 106: radiation dose to patients from radiopharmaceuticals, a third addendum to ICRP publication 53. *Ann ICRP.* 2008;38(1–2).
6. Russell JR, Stabin MG, Sparks RB, Watson E. Radiation absorbed dose to the embryo/fetus from radiopharmaceuticals. *Health Phys.* 1997;73:756–769.

VIII. APPROVAL

This practice guideline (version 6.0) was approved by the Board of Directors of the SNM on June 8, 2012. Version 1.0 was approved on February 12, 1995; version 2.0 on February 7, 1999; version 3.0 on June 23, 2001; version 4.0 on June 6, 2010; and version 5.0 on September 12, 2010.

APPENDIX

Example of Radiation Dosimetry Tables from the SNM Guideline for Lung Scintigraphy 4.0 (2011)

Radiation dosimetry in adults, 5-y-old children, and the fetus are presented in Tables 1–6. [**Table 1**]

Regarding the breastfeeding patient, ICRP Publication 106 (*6*) suggests a 12-h interruption of breast feeding for subjects receiving 150 MBq (4.1 mCi) of ^{99m}Tc-MAA; it does not provide a recommendation about interruption of breastfeeding for ^{99m}Tc-DTPA aerosols (but suggests that no interruption is needed for ^{99m}Tc-DTPA intravenously administered or ^{99m}Tc-Technegas [Cyclomedica Ltd.]); the authors recommend that no interruption is needed for breastfeeding patients administered ^{133}Xe or ^{81m}Kr. [**Table 2**] [**Table 3**] [**Table 4**] [**Table 5**] [**Table 6**]

TABLE 1
Radiation Dosimetry in Adults

Radiopharmaceutical	Administered activity		Largest radiation dose			Effective dose*	
	MBq	mCi	Organ	mGy/MBq	rad/mCi	mSv/MBq	rem/mCi
^{99m}Tc-MAA†	40–150	1.1–4.1	Lung	0.067	0.25	0.011	0.041
^{99m}Tc-DTPA‡	20–40	0.54–1.1	Bladder	0.047	0.17	0.0061	0.023
^{133}Xe§	200–750	5.4–20	Lung	0.0011	0.0041	0.00071	0.0026
^{81m}Kr‖	40–400	1.1–11	Lung	0.00021	0.00078	0.000027	0.0001

*Data are from (*3*).
†Data are from (*2*), page 224.
‡Data are from (*2*), page 218.
§Data are from (*2*), page 345, rebreathing for 5 min.
‖Data are from (*2*), page 160.

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TABLE 2
Radiation Dosimetry in Children (5 Years Old)

Radiopharmaceutical	Administered activity		Largest radiation dose			Effective dose	
	MBq/kg	mCi/kg	Organ	mGy/MBq	rad/mCi	mSv/MBq	rem/mCi
^{99m}Tc MAA*	0.5–2	0.014–0.054	Lung	0.21	0.78	0.038	0.14
^{99m}Tc DTPA†	0.4–0.6	0.011–0.016	Bladder	0.12	0.44	0.020	0.074
^{133}Xe‡	10–12	0.27–0.32	Lung	0.0037	0.014	0.0027	0.010
^{81m}Kr§	0.5–5	0.014–0.14	Lung	0.00068	0.0025	0.000088	0.00033

*Data are from (*2*), page 224.
†Data are from (*2*), page 218.
‡Data are from (*2*), page 345, rebreathing for 5 min.
§Data are from (*2*), page 160.

TABLE 3
^{99m}Tc MAA: Dose Estimates to the Fetus

Stage of gestation	Fetal dose			
	mGy/MBq	rad/mCi	mGy*	rad*
Early	0.0028	0.010	0.11–0.42	0.011–0.042
3 mo	0.0040	0.015	0.16–0.60	0.016–0.060
6 mo	0.0050	0.018	0.20–0.75	0.020–0.075
9 mo	0.0040	0.015	0.16–0.60	0.016–0.060

*Maternal administered activity, 40–150 MBq (1.1–1.4 mCi).
Data are from Russell et al. (*7*). No information about possible placental crossover of this compound was available for use in estimating fetal doses.

TABLE 4
^{99m}Tc DTPA Aerosol: Dose Estimates to the Fetus

Stage of gestation	Fetal dose			
	mGy/MBq	rad/mCi	mGy*	rad*
Early	0.0058	0.021	0.12–0.23	0.012–0.023
3 mo	0.0043	0.016	0.086–0.17	0.0086–0.017
6 mo	0.0023	0.0085	0.046–0.092	0.0046–0.0092
9 mo	0.0030	0.011	0.060–0.12	0.0060–0.012

*Maternal administered activity, 20–40 MBq (0.54–1.1 mCi).
Data are from Russell et al. (*7*). Information about possible placental crossover of this compound was available and was considered in estimates of fetal doses.

TABLE 5
^{133}Xe: Dose Estimates to the Fetus

Stage of gestation	Fetal dose			
	mGy/MBq	rad/mCi	mGy*	rad*
Early	0.00025	0.00092	0.050–0.19	0.0050–0.019
3 mo	0.000029	0.00011	0.0058–0.022	0.00058–0.0022
6 mo	0.000021	0.000078	0.0042–0.016	0.00042–0.0016
9 mo	0.000016	0.000059	0.0032–0.01	0.00032–0.0012

*Maternal administered activity, 200–750 MBq (5.4–20 mCi).
Data are from Russell et al. (*7*). No information about possible placental crossover of this compound was available for use in estimating fetal doses.

TABLE 6
^{81m}Kr: Dose Estimates to the Fetus

Stage of gestation	Fetal dose			
	mGy/MBq	rad/mCi	mGy*	rad*
Early	1.8×10^{-7}	6.7×10^{-7}	7.2×10^{-6} to 7.2×10^{-5}	7.2×10^{-5} to 7.2×10^{-6}
3 mo	1.8×10^{-7}	6.7×10^{-7}	7.2×10^{-6} to 7.2×10^{-5}	7.2×10^{-5} to 7.2×10^{-6}
6 mo	2.8×10^{-7}	1.0×10^{-6}	1.1×10^{-5} to 1.1×10^{-4}	1.1×10^{-6} to 1.1×10^{-5}
9 mo	3.4×10^{-7}	1.3×10^{-6}	1.4×10^{-5} to 1.4×10^{-4}	1.4×10^{-6} to 1.4×10^{-5}

*Maternal administered activity 40–400 MBq (1.1–11 mCi).

Dose estimates to the fetus were not provided by Russell et al. (*7*) but were estimated using kinetic data in ICRP 53. No information about possible placental crossover of this compound was available for use in estimating fetal doses.

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