**From:** William R. Uffelman <wuffelman@snm.org>
**To:** <nrcrep@nrc.gov>
**Date:** Tue, Jun 4, 2002 9:55 AM
**Subject:** Response from "Contact the Web Site Staff"



The following information was submitted by
William R. Uffelman (wuffelman@snm.org) on Tuesday, June 4, 2002 at 09:54:18
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Document_Title: NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Medical Use Licenses"

4/5/02
67FR16467
(5)

Comments: June 3, 2002

Chief, Rules and Directives Branch
Division of Administrative Services
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: NUREG-1556, Volume 9, ''Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Medical Use Licenses"

Dear Sir/Madam:

I am writing in response to the Federal Register notice concerning NUREG-1556, Volume 9, " Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Medical Use Licenses". I am pleased to submit the following on behalf of the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM). ACNP and SNM are professional associations representing more than 13,000 physicians, scientists and technologists who specialize in nuclear medicine.

On April 25 and April 30, SNM's President, Alan Maurer, M.D., ACNP/SNM Joint Government Relations Chair, Jeffry Siegel, PhD, and I participated in the facilitated workshops held at NRC's headquarters to discuss the guidance as applied to therapeutic and diagnostic nuclear medicine. We were active participants during those two sessions and understand that the comments and recommendations made then will be made part of the record on NUREG-1556, Volume 9. We came away from the sessions with the feeling that our concerns about the draft guidance had been fully aired and were understood by the NRC staff.

During the sessions it was suggested that societies could offer guidance for their specialty that could be reviewed and accepted by the NRC. In a later teleconference with NRC staff, this offer was reaffirmed and we were invited to submit an outline or draft of any proposed guidance document prior to the close of the comment period.

Attached to this letter, please find an outline for a book to be published this year entitled "Nuclear Regulatory Commission Regulation of Nuclear Medicine: How diagnostic Nuclear Medicine Licensees Can Comply With the Newly Revised Regulations In 10 CFR Part 35." It is our understanding that when completed the book it will be reviewed by NRC staff, and if found to be complete and correct, a licensee may rely on the specialty society guidance in complying with 10 CFR Part 35. Because time is of the essence in the timely completion of this project it is also our understanding that NRC staff will review this outline as to sufficiency of the book's coverage.

We appreciate this opportunity to comment on the proposed NUREG-1556, Volume 9, and to participate in the effort to implement 10 CFR Part 35 in the most efficient manner possible. We look forward to completing the proffered book and working with the NRC staff during the implementation phase.

Template = ADM-013

E-RIDS = ADM-03
Add = R. Broseus (RWB)

Thank you for your consideration.

Sincerely,

William R. Uffelman
General Counsel and Director of Public Affairs
American College of Nuclear Physicians and Society of Nuclear Medicine

703-708-9773

Book Outline

NUCLEAR REGULATORY COMMISSION REGULATION OF
NUCLEAR MEDICINE: HOW DIAGNOSTIC NUCLEAR MEDICINE LICENSEES CAN COMPLY WITH
THE NEWLY REVISED REGULATIONS IN 10 CFR PART 35

Jeffry A. Siegel, Ph.D.
Chair, ACNP/SNM Joint Government Relations Committee

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I. Introduction

The purpose of this book is to provide guidance, that conforms to current NRC requirements, to diagnostic nuclear medicine applicants and/or licensees in the preparation and/or amendment or renewal of a license for the medical use of byproduct material issued by the Nuclear Regulatory Commission (NRC) under the newly revised, risk-informed and performance-based, 10 CFR Part 35, Medical Use of Byproduct Material. The regulations require that applicants and/or licensees develop, document, and implement operating policies and procedures as part of an overall radiation protection program that will ensure compliance with the regulations and the security and safe use of licensed materials. These provisions are neither detailed in the regulations nor required to be submitted as part of the license application. Some diagnostic nuclear medicine practitioners develop their own radiation protection procedures while most rely on procedures published by the NRC in documents such as NU!
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REG-1556, Volume 9, Consolidated Guidance About Material Licenses. This heavy reliance on NRC licensing "guidance" is due to the fact that the required procedures will first be examined during an inspection. Thus, the Commission's guidance is likely to become de facto regulation, thereby undermining the goal of providing licensees with additional flexibility.

The suggested operating policies and procedures that will be contained in this book represent the first attempt by a stakeholder to develop a stand alone document applicable to the practice of diagnostic nuclear medicine, containing not only licensing guidance but also all pertinent NRC requirements.

Currently, NRC requirements and licensing guidance for diagnostic and therapeutic medicine are intermingled. This book will also detail how some of the suggested procedures might be revised, or even eliminated, based on the licensee's review of their radiation protection program.

The reader of this book will have for the first time, all the NRC regulations applicable to diagnostic nuclear medicine and guidance for developing operating policies and procedures to comply with these requirements, in one place. It is hoped that all nuclear practitioners who have not be able to "muddle" through these regulations due to inconvenience, will now take the time to read all the requirements and suggested operating policies and procedures, which represent all the necessary "tools" for compliance. In so doing, this book should serve not only as a valuable educational experience but also as a resource for the entire diagnostic nuclear medicine community to use in the license application process and in the development of their own radiation protection programs.

The remaining chapters will contain:

II. The Practice of Diagnostic Nuclear Medicine

A brief summary of the practice of diagnostic medicine, giving a typical facility layout and items necessary to ensure the safe use of radioactive materials and demonstrate compliance with applicable NRC regulations. The safety of nuclear medicine will be emphasized and radiation doses received by patients will be given.

III. Brief History of AEC and NRC Regulation of Nuclear Medicine

A brief history of the federal regulation of nuclear medicine, from its beginnings during the Manhattan Project up to the present including important events such as, the congressional passage of the Atomic Energy Act in 1946 creating the Atomic Energy Commission and the congressional passage of the Energy Reorganization Act creating the Nuclear Regulatory Commission.

IV. Overview of NRC Regulations Applicable to Medical Use Licensees

This book will cover licensing guidance and the major Parts of Title 10 of the Code of Federal Regulations that are applicable to diagnostic nuclear medicine licensees, namely Parts 19, 20, 30, and 35. Also, the impact of the NRC's regulatory framework, consisting of several interrelated documents, including Title 10, statements of policy, and licensing and inspection guidance will be discussed.

V. NRC and Agreement States

The regulatory authority of the NRC and the individual states will be presented. The difference between NRC and Agreement states will be discussed.

VI. NRC Licenses for Medical Use

The 3 types of licensees issued by the NRC will be discussed.

VII. Revised Part 35 Requirements Applicable to Diagnostic Nuclear Medicine

Currently Part 35 intermingles requirements for diagnostic and therapeutic medicine. As a first step in making these requirements more "user-friendly", only those requirements applicable to diagnostic nuclear medicine uses will be identified. Essentially all of these requirements will be covered in the following chapters.

VIII. Training and Experience Requirements for Diagnostic Nuclear Medicine

NRC training and experience requirements to demonstrate sufficient knowledge and skills in radiation protection practices and procedures for the following individuals will be detailed: Authorized User Physician (AU), Radiation Safety Officer (RSO), Authorized Nuclear Pharmacist (ANP), and Authorized Medical Physicist (AMP). It will also be discussed that due to certain unintended consequences of the revised Part 35, the rule includes a two-year transition period for training and experience requirements during which time the current or revised requirements can be used.

IX. Radiation Protection Program

Key elements for a radiation protection program will be detailed addressing each of the following:

A. Occupational Dose Limits
B. Dose Limits for Members of the Public
C. Minimization of Contamination/Spill Procedures
D. Material Receipt and Accountability/Ordering, Receiving, and Opening Packages
E. Radiation Surveys and Calibration of Survey Instruments
F. Caution Signs and Posting Requirements
G. Labeling Vials and Syringes
H. Measuring Patient Dosages
I. Sealed Source Inventory and Leak Testing
J. Waste Disposal and Decay-In-Storage
K. Records
L. Reports
M. Safety Instruction for Workers
N. Audit Program

Each section in this chapter will provide the following:
1. All pertinent NRC requirements for the medical use of byproduct material in the practice of diagnostic nuclear medicine;
2. A discussion of the requirements; and
3. Suggested procedures for compliance.

In light of the NRC's new risk-informed, performance-based approach to regulation, it will be emphasized that the continued need for some of the procedures given in this book should be based on the diagnostic nuclear medicine licensee's own prior experience. Guidance will be given as to how some of the suggested procedures might be revised, or even eliminated.

X. License Application

The license application process will be described and guidance will be given to diagnostic nuclear medicine applicants by providing suggested responses for each of the 13 items required in NRC Form 313, which is the actual application.

XI. License Amendments and/or Renewals

Procedures for requesting a license amendment or renewal from the NRC will be presented.

XII. Appendices

Sample records and reports that can be used by nuclear medicine licensees to comply with applicable NRC requirements will be included.

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SUBMIT2: Send Questions or Comments

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