

AUG 02 1991

AD 69-1
PDR
9

Mr. Sam Kalman, Board Secretary
Board of Pharmaceutical Specialties
2215 Constitution Avenue, NW
Washington, DC 20037

Dear Mr. Kalman:

In a letter dated July 19, 1991 inviting your organization to participate in the workshop on "authorized radiopharmacist," we stated that we would present a proposed strawman. A draft of our proposed strawman is enclosed for your consideration.

We would appreciate it if the participants would review the proposed strawman and be prepared to discuss it and offer alternative solutions for these topics with the supporting rationale during the workshop.

Instead of Mr. David Laven, Mr. Henry Chilton will represent the American Society of Hospital Pharmacists.

I am looking forward to meeting the participants at the workshop on August 7, 1991.

Sincerely,

John Telford, Chief
Rulemaking Section
Regulation Development Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

Enclosure:
Draft strawman

DISTRIBUTION: (w/encl.)
Subj-circ-chron
RDB reading file (SBahadur)
BMorris
FCostanzi
JTelford
ATse
JGlenn, NMSS
LCamper, NMSS
LBolling, GPA

IDENTICAL LETTERS SENT TO THOSE
ON ENCLOSED LIST

OFF: RDB/DRA/RES
NAME: ATse
DATE: 7/30/91

RDB/DRA/RES
JTelford
7/30/91

OFFICIAL RECORD COPY

9309200140 930908
PDR PR
30 58FR33396 PDR

930920140

Identical Letters Sent To:

Mr. Sam Kalman, Board Secretary
Board of Pharmaceutical Specialties
2215 Constitution Avenue, NW
Washington, DC 20037

Dr. Homer Hupf, President
American Board of Science in Nuclear Medicine
3341 Cadencia Street
Carlsbad, Ca 92009

Mr. Carmen A. Catizone, Executive Director
National Association of Boards of Pharmacy
1300 Higgins Road
Park Ridge, IL 60068

Mr. Henry Kramer, Chairman
Committee on Radionuclides and
Radiopharmaceuticals
US Council for Energy Awareness
3911 Campolindo Drive
Moraga, CA 94556

Dr. Dennis Eshima
College of Pharmacy
Radiopharmacy
University of New Mexico
Albuquerque, NM 87131

Mr. Dennis Swanson
School of Pharmacy
1111 Salk Hall
University of Pittsburgh
Pittsburgh, PA 15261

Ms. Anne Smith, Director
Nuclear Pharmacy Program
School of Pharmacy and Pharmaceutical Sciences
Purdue University
Robert E. Heine Pharmacy Building
West Lafayette, IN 47907

Mr. Brian Hyps
Associate Director for Government Affairs
American Pharmaceutical Association
2215 Constitution Avenue, NW
Washington, DC 20037

Ms. Beverly Black, Director
Federal Regulatory Affairs
American Society of Hospital Pharmacists
4630 Montgomery Avenue
Bethesda, MD 20814

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 1 - ACCEPTED CERTIFICATIONS.

**AN "AUTHORIZED RADIOPHARMACIST" IS A PHARMACIST WHO IS
CURRENTLY CERTIFIED AS A NUCLEAR PHARMACY SPECIALIST BY THE
BOARD OF PHARMACEUTICAL SPECIALTIES OF THE AMERICAN
PHARMACEUTICAL ASSOCIATION.**

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 2 - EDUCATION AND EXPERIENCE CRITERIA IN LIEU OF CERTIFICATION.

AN "AUTHORIZED RADIOPHARMACIST" IS A PHARMACIST WHO HAS:

- (a) EITHER A B.S. DEGREE IN PHARMACY OR PHARM. D. FROM A SCHOOL
OF PHARMACY ACCREDITED BY THE AMERICAN COUNCIL ON
PHARMACEUTICAL EDUCATION;**
- (b) A CURRENT LICENSE TO PRACTICE PHARMACY;**
- (c) 4000 HOURS OF PROFESSIONAL EXPERIENCE IN NUCLEAR PHARMACY
PRACTICE IN A LICENSED NUCLEAR PHARMACY OR HEALTH-CARE
FACILITY APPROVED BY AN AGREEMENT STATE OR THE NRC TO**

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 2 - EDUCATION AND EXPERIENCE CRITERIA IN LIEU OF CERTIFICATION. (CONTINUED)

**HANDLE BYPRODUCT MATERIALS, AND EXPERIENCE CREDIT MAY BE
GRANTED FOR UP TO 2,000 HOURS ACCORDING TO THE FOLLOWING:**

- (i) PHARMACISTS WHO HAVE COMPLETED A PH.D OR M.S. PROGRAM
IN NUCLEAR PHARMACY MAY BE GRANTED UP TO 2,000 HOURS
EXPERIENCE CREDIT,**
- (ii) PHARMACISTS WHO HAVE COMPLETED UNDERGRADUATE OR
POSTGRADUATE COURSES IN NUCLEAR PHARMACY MAY BE
GRANTED UP TO 100 HOURS PER QUARTER HOUR OR 150 HOURS**

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 2 - EDUCATION AND EXPERIENCE CRITERIA IN LIEU OF CERTIFICATION. (CONTINUED)

PER SEMESTER HOUR UP TO A MAXIMUM OF 1,500 HOURS

EXPERIENCE CREDIT,

(iii) PHARMACISTS WHO HAVE PARTICIPATED IN RESIDENCY

PROGRAMS IN NUCLEAR PHARMACY MAY BE GRANTED CREDIT ON

AN HOUR-FOR-HOUR BASIS FOR TIME SPENT IN ACTUAL NUCLEAR

PHARMACY PRACTICE UP TO A MAXIMUM OF 2,000 HOURS

EXPERIENCE CREDIT, AND

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 2 - EDUCATION AND EXPERIENCE CRITERIA IN LIEU OF CERTIFICATION. (CONTINUED)

- (iv) PHARMACISTS WHO HAVE PARTICIPATED IN INTERNSHIP
PROGRAMS TO SATISFY REQUIREMENTS OF STATE BOARDS OF
PHARMACY MAY BE GRANTED CREDIT ON AN HOUR-FOR-HOUR
BASIS FOR TIME SPENT IN ACTUAL NUCLEAR PHARMACY PRACTICE
UP TO A MAXIMUM OF 2,000 HOURS EXPERIENCE CREDIT; AND

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 2 - EDUCATION AND EXPERIENCE CRITERIA IN LIEU OF CERTIFICATION. (CONTINUED)

- (d) 1000 HOURS OF SYSTEMATIC INSTRUCTION BY AN AUTHORIZED RADIOPHARMACIST AT A NUCLEAR PHARMACY WITH A MINIMUM OF 100 HOURS FOR EACH OF THE FOLLOWING:
 - (i) PROCUREMENT OF RADIOPHARMACEUTICALS,
 - (ii) COMPOUNDING OF RADIOPHARMACEUTICALS,
 - (iii) PERFORMANCE OF APPROPRIATE QUALITY-CONTROL PROCEDURES,
 - (iv) DISPENSING OF RADIOPHARMACEUTICALS,

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 2 - EDUCATION AND EXPERIENCE CRITERIA IN LIEU OF CERTIFICATION. (CONTINUED)

- (v) DISTRIBUTION OF RADIOPHARMACEUTICALS,**
- (vi) IMPLEMENTATION OF BASIC RADIATION PROTECTION PROCEDURES
AND PRACTICES, SUCH AS, PERSONNEL MONITORING, RECEIPT OF
RADIOACTIVE MATERIALS, CHECKING SURVEY METERS FOR
PROPER OPERATION, PERFORMING RADIATION SURVEYS,**

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 2 - EDUCATION AND EXPERIENCE CRITERIA IN LIEU OF CERTIFICATION. (CONTINUED)

STORAGE, TRANSFER, SHIELDING, SECURITY, SAFETY, EQUIPMENT
CALIBRATION, ENVIRONMENTAL MONITORING, RADIOACTIVE
WASTES, POSTING OF AREAS, AND EVALUATION OF RADIATION
PROTECTION, AND

(vii) CONSULTATION PROVIDED TO THE NUCLEAR MEDICINE
COMMUNITY, PHARMACISTS, PATIENTS,

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 2 - EDUCATION AND EXPERIENCE CRITERIA IN LIEU OF CERTIFICATION. (CONTINUED)

**OTHER HEALTH PROFESSIONALS, AND THE GENERAL PUBLIC
REGARDING:**

- (1) THE PHYSICAL AND CHEMICAL PROPERTIES OF
RADIOPHARMACEUTICALS,**
- (2) PHARMACOKINETICS AND BIODISTRIBUTION OF
RADIOPHARMACEUTICALS, AND**
- (3) DRUG INTERACTIONS AND OTHER FACTORS THAT ALTER
PATTERNS OF DISTRIBUTION.**

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

**TOPIC 3 - SUPERVISION OF PHARMACISTS OR INDIVIDUALS WORKING AS
PHARMACISTS PROVIDED BY AN AUTHORIZED RADIOPHARMACIST.**

THE AUTHORIZED RADIOPHARMACIST SHALL:

- (a) INSTRUCT THE SUPERVISED INDIVIDUAL IN THE PRACTICE OF NUCLEAR
PHARMACY AND THE PRINCIPLES OF RADIATION SAFETY;**
- (b) DEVELOP AND IMPLEMENT APPROPRIATE PROCEDURES TO ENSURE
THAT THE RIGHT RADIOPHARMACEUTICAL IN THE RIGHT DOSAGE FORM
IS PREPARED AND LABELED CORRECTLY FOR:**

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

**TOPIC 3 - SUPERVISION OF PHARMACISTS OR INDIVIDUALS WORKING AS
PHARMACISTS PROVIDED BY AN AUTHORIZED RADIOPHARMACIST.
(CONTINUED)**

- (i) DIAGNOSTIC AND THERAPEUTIC RADIOPHARMACEUTICAL
DOSAGES GREATER THAN 30 MICROCURIES OF EITHER SODIUM
IODIDE I-125 OR I-131, AND**
- (ii) ALL OTHER THERAPEUTIC RADIOPHARMACEUTICALS;**

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

**TOPIC 3 - SUPERVISION OF PHARMACISTS OR INDIVIDUALS WORKING AS
PHARMACISTS PROVIDED BY AN AUTHORIZED RADIOPHARMACIST.
(CONTINUED)**

- (c) REQUIRE THE SUPERVISED INDIVIDUAL TO FOLLOW THE INSTRUCTIONS OF THE AUTHORIZED RADIOPHARMACIST, AND TO COMPLY WITH THE REGULATIONS OR LICENSE CONDITIONS OF NRC (THE LICENSEE MAY BE SUBJECT TO OTHER FEDERAL REQUIREMENTS APPLICABLE TO RADIOPHARMACEUTICALS);
- (d) PERIODICALLY REVIEW THE SUPERVISED INDIVIDUAL'S WORK;
- (e) BE RESPONSIBLE FOR THE ACTS AND OMISSIONS OF THE SUPERVISED INDIVIDUAL IN THE PRACTICE OF NUCLEAR PHARMACY;

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

**TOPIC 3 - SUPERVISION OF PHARMACISTS OR INDIVIDUALS WORKING AS
PHARMACISTS PROVIDED BY AN AUTHORIZED RADIOPHARMACIST.
(CONTINUED)**

- (f) PROVIDE SUPERVISION FOR ROUTINE COMPOUNDING BY:**
 - (i) APPROVING A PROCEDURES MANUAL FOR THE PREPARATION OF
RADIOPHARMACEUTICALS TO BE USED BY THE SUPERVISED
INDIVIDUAL AND BEING AVAILABLE FOR CONSULTATION
WHENEVER NEEDED, OR**
 - (ii) BEING PHYSICALLY PRESENT IN THE NUCLEAR PHARMACY DURING
THE COMPOUNDING; AND**

DRAFT REGULATORY APPROACH FOR ESTABLISHING AN "AUTHORIZED RADIOPHARMACIST"

TOPIC 3 - SUPERVISION OF PHARMACISTS OR INDIVIDUALS WORKING AS
PHARMACISTS PROVIDED BY AN AUTHORIZED RADIOPHARMACIST.
(CONTINUED)

- (g) PROVIDE DIRECT SUPERVISION FOR NON-ROUTINE COMPOUNDING BY:
 - (i) BEING IN THE PHYSICAL PRESENCE OF THE INDIVIDUAL
PERFORMING THE COMPOUNDING IN ORDER TO ALLOW
OBSERVANCE AND DIRECT SUPERVISION, AND
 - (ii) LIMITING THE DIRECT SUPERVISION TO A MAXIMUM OF 6
INDIVIDUALS.