Errata

UNITED STATES

October 29, 1976 NUCLEAR REGULATORY COMMISSION SECY 76-529

INFORMATION REPORT

For: The Commissioners

From: Robert B. Minogue, Director, Office of Standards Development and Kenneth R. Chapman, Director, Office of Nuclear Materials Safety and Safeguards

Thru: Executive Director for Operations

Subject: THE ISSUES CONCERNING NRC INVOLVEMENT IN THE REGULATION OF NUCLEAR MEDICINE

Purpose: To provide the opportunity to brief the Commission on the key issues concerning NRC's involvement in regulating nuclear medicine.

Discussion: As a part of the Commission's review of NRC regulations, the staff is preparing a paper which will identify the key issues concerning NRC's present and future involvement in regulating nuclear medicine. This task includes (1) providing a historical perspective on AEC-NRC policies regarding nuclear medicine; (2) describing the NRC's current involvement in the regulation of nuclear medicine, as well as the often overlapping activities of other federal, state, and private agencies; (3) identifying the key issues; and (4) recommending a future course of action for NRC. The first steps are accomplished, and the staff desires to brief the Commission on the key issues before a recommendation is prepared. We believe that it would be advantageous to obtain a sense of the Commission on the key issues before proceeding to develop a staff recommendation.

Coordination: The briefing materials enclosed in this paper have been coordinated with the Offices of Inspection and Enforcement, State Programs and the Executive Legal Director.

Robert B. Minogue, Director
Office of Standards Development

Kenneth R. Chapman, Director
Office of Nuclear Materials Safety and Safeguards

Enclosure:
Materials for Commission Briefing on Nuclear Medicine

Contact:
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SECY NOTE: This briefing will be scheduled in the near future.

Docket

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MH 5-18 (Research)
BP

E. Podolak 10/14/76

BACKGROUND ON THE REGULATORY CONTROL OF NUCLEAR MEDICINE

PREFACE

The Staff has identified, in this preface, some key issues that can be considered in review of the discussion of nuclear medicine which follows.

The Food and Drug Administration (FDA) is recognized as being the lead agency in regulating nuclear medicine. However, FDA is limited by its statutory authority to regulating the manufacture of drugs and devices (including radioactive drugs and devices) offered for interstate commerce. The FDA does not have the authority to regulate the use of a drug or device. In contrast, the NRC's statutory authority to regulate byproduct, source and special nuclear material is not limited in this area and can cover all aspects of both the manufacture and use of drugs and devices involving such materials. This basic difference in regulatory authority emphasizes the central issue, "How far does NRC want to go in regulating nuclear medicine?".

The NRC program of control to protect the health and safety of the worker, the patient and the general public in the medical uses of byproduct, source and special nuclear material is basically a licensing program. The NRC licenses the possession and use of such materials by manufacturers, distributers, pharmacies, researchers, medical institutions and private physicians. The licensing program consists of four steps, (1) the license application, (2) staff review, (3) granting the license with certain conditions (or denying the license) and (4) inspection and enforcement.

Under NRC regulations a prospective licensee must submit an application for a license which contains basic information[1] concerning the available facilities and equipment, the radiation safety program and the users qualifications. An applicant for the human use of byproduct material submits supplemental information[2] pertaining to the purpose for which the licensed material will be used (specific conditions to be diagnosed or treated), special equipment and facilities, and the users clinical experience.

The NRC Staff reviews the license application to determine the applicant's ability, (1) to satisfy NRC regulations, (2) to provide radiation safety for employees and the public and (3) to limit offsite releases.

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[1] Basic information in the byproduct material license application includes:
(a) The names, training and experience of individual users;
(b) The name, training and experience of the radiation safety officer;
(c) Possession limits for each radioisotope;
(d) Purposes for use;
(e) Number, type, method and frequency of calibration for radiation detection instruments;
(f) Facilities and Equipment;
(g) Radiation Protection Program;
(h) Waste disposal.

[2] Supplemental information for human use includes:
(a) Using physician's name, clinical training and experience and radioisotope handling training and experience;
(b) Specific conditions or diseases to be diagnosed and treated;
(c) Investigative proposals for experimental or non-routine use;
(d) Quality assurance procedures for material not obtained in pre-calibrated dosage form;
(e) Description of dose calibrators and diagnostic instrumentation;
(f) Method and frequency of calibration of survey instruments and dose calibrators.

A license is granted if after a thorough review, the staff determines that the applicant has met the criteria in the regulations and can carry out the proposed activities safely. The licensee is required to comply with the applicable NRC regulations and all conditions in the license. License conditions include portions of the license application.

Follow-up inspections of licensees for compliance with NRC regulations and license conditions are conducted on a scheduled sampling basis.

Some specific issues related to the central issue are:

1. Should the NRC evaluate physicians qualifications?
   - radiation safety qualifications? - clinical qualifications?
2. Should the NRC place restrictions on the use by a physician of radioactive drugs or devices that have been approved by FDA?
3. Should the NRC require a physician to report the misadministration of radioactive material or radiation from radioactive material to the NRC?
   - to the patient or a responsible relative?
4. Should the NRC evaluate the qualifications of paramedical personnel, such as, technologists, nurses and radiological physicists? Should the review be limited to radiation safety qualifications?
5. Should the NRC ensure that the patient receives what is prescribed? (e.g., by requiring the periodic calibration of teletherapy devices, or the use of dose calibrators to measure all doses of radioactive drugs prior to administration, or the periodic calibration of diagnostic equipment, such as, scanners and gamma cameras to minimize "retakes"?)

Clearly this list is not exhaustive.

BACKGROUND ON THE REGULATORY CONTROL OF NUCLEAR MEDICINE

I. INTRODUCTION

The practice of medicine involves two broad areas: clinical medicine (diagnosis and treatment of disease) and biomedical research (study of normal body function and the disease process).

The use of radioisotopes in medicine started in the mid 1920's, when clinicians used isotopes of radium, a naturally occurring radioisotope, to determine the velocity of the blood flow by measuring the transit time from arm to arm. The measurements were made in both normal persons and patients with various diseases. Blood circulation measurements remain a important tool of diagnostic nuclear medicine, which, over the years, has grown to include such techniques as (1) measuring the uptake of radioactive drugs by individual organs (for such purposes as assessing thyroid function); (2) "imaging" or measuring the distribution of radioactive drugs among organs or within an organ (to detect the presence of tumors, for example); (3) estimating the size of certain body pools (such as red blood cell and blood plasma volumes); and (4) measuring the components in biological samples (such as protein binding sites and hormones in blood and urine). The first three examples of diagnostic use are termed in vivo (inside the body), since radioactive drugs are administered to the patient. The fourth example, measuring the components of biological samples, is termed in vitro (outside the body), since the assay is performed in a test tube in a clinical laboratory and no radioisotope is introduced into the patient.

The therapeutic aspect of nuclear medicine involves the use of radioactive substances to treat both malignant and non-malignant diseases and disorders. Therapeutic techniques include (1) the use of radioactive drugs internally (for example the treatment of hyperthyroidism); (2) the use of the use of radioactive devices both as implants and on the surface of the body (termed "brachytherapy" or therapy from a short distance); and (3) the use of radioactive devices external to the body (termed "teletherapy" or therapy from a distance).

Nuclear medicine has provided a battery of new tools for both the clinician and the researcher and has grown from 38 medical institutions using radioisotopes in 1946 to 6346 NRC licenses[1] and an equivalent number of NRC Agreement State licenses[2]. Based on discussions with the industry and other agencies, the Staff has estimated 30 million nuclear medicine procedures per year[3] are conducted at an estimated cost of 1.6 billion dollars[4].

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[1] 1,355 medical institution licenses
701 private practice licenses
470 teletherapy licenses
3,820 general licenses for medical use.

[2] 3,967 Agreement State medical licenses (institution and private practice). Data on general medical licenses not available, not all Agreement States have general licenses.

[3] Breakdown of nuclear medicine procedures:
13 million in vivo radioactive drug
10 million in vitro diagnostic
7 million teletherapy (.3 million patients/year x 25 procedures/patient) plus an unknown number of brachytherapy procedures

Breakdown of cost:
$100 million in vivo and in vitro sales
$ 89 million diagnostic imaging and scanning device, sales
$1.15 billion for 23 million in vivo and in vitro procedures assuming an average of $50 per procedure, (exclusive of materials and equipment costs)
$300 million for teletherapy ($1000 per patient)

The major steps involved in the nuclear medicine industry are:

- Production of the radioisotope, usually by irradiation of stable elements in an accelerator or nuclear reactor. Chemical separation of the radioisotope from the target material may be necessary.

  A few manufacturers of the final drug or device have their own radioisotope production facilities (both reactors and accelerators). A few medical institutions use accelerators to produce very short-lived radioisotopes.

- Manufacture of the final radioactive drug or device. In the manufacture of an *in vivo* radioactive drug or an *in vitro* test kit, the radioisotope is combined (often in complicated chemical processes) with the non-radioactive components and packaged for delivery to the user. For brachytherapy devices, the radioisotope may be alloyed with or encapsulated in an inert material in the form of a "seed", "needle" or "plaque". For teletherapy devices, the radioisotope (usually ^{60}Co or ^{137}Cs) is doubly encapsulated and then enclosed in a heavy shield for transportation and use.

  In the U.S., 6 major radiopharmaceutical houses produce most of the prepackaged radioactive drugs and *in vitro* diagnostics used in most medical institutions, clinical laboratories and private (physician) offices.

  A grey area in the manufacture of radioactive drugs and devices is the "nuclear pharmacy." The activities of nuclear pharmacies range from performing simple manipulations, such as

measuring out individual doses of radioactive drugs which have been manufactured elsewhere, to performing complex medical procedures and preparing radioactive drugs from raw materials. Their business may extend from servicing a single medical institution to dispensing radioactive drugs to an entire geographic region and in most cases, their activities are carried out within the state borders in which they are located. There is no clean line to decide when a nuclear pharmacy has gone beyond the ordinary practice of pharmacy (compounding and dispensing), and becomes a manufacturer, a determination of most importance to the Food and Drug Administration.

- Distribution of the radioactive drug or device. The radioactive drug or device is transported between the manufacturer and the user (medical institution, clinical laboratory and the physician's private office) by commerical transportation (passenger and cargo aircraft, train, bus, truck and taxi) and private auto. The inner packages are often shielded and the inner and outer containers are labeled. Transportation of radioactive drugs is the largest contribution to the total population exposure from the normal transportation of radioactive material (NUREG-0034). A part of the distribution process for teletherapy devices includes the installation of the device in specially shielded rooms by NRC and Agreement State licensed service companies.

- Use of the radioactive drug or device can be as simple as placing a radioactive capsule into a patient's mouth or drawing a prepared radioactive drug into a syringe and injecting it into

a patient. The use of a radioactive drug may involve "eluting" a radioisotope generator[3] combining the radioisotope with a chemical reagent[4] to produce the final dosage form. The drug then can be drawn up into a syringe and injected into the patient. Technicians and nurses assist the physician who is primarily responsible for the delivery of the nuclear medicine service to the patient. The preparation of the radioactive drug is usually either by a technician or a pharmacist, and the injection is usually performed by technicans or nurses when state and local laws permit. The diagnostic equipment (i.e scanners and scintillation "cameras") often are operated by technicians. Technicians also operate the teletherapy devices.

- Disposal of the radioactive drugs and devices usually follows the traditional methods of decay, dilution and dispersal through the sewage system, or collection and land burial. The most widely used radioactive drug (^{99m}Tc) has a half-life of 6 hours and the waste material is often held for decay and disposed as non-radioactive waste. Patients excrete much of the administered radioactive drug which usually goes directly into the sewer. However, sealed sources in teletherapy and brachytherapy are used over and

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[3] A radioisotope generator (or "cow") is a shielded device purchased from a drug manufacturer containing a parent-daughter radioisotope (such as Mo-99 - Tc-99m). The radioisotope is adsorbed on a column that is arranged so a solution can be fed through the column to wash out ("elute") only the daughter radioisotope (Tc-99m). The parent has a longer half-life than the daughter and continuously "generates" the daughter radioisotope which is eluted when needed. The Mo-99 - Tc-99m generator is usually eluted every 24 hours and replaced once a week (because the parent has decayed below useful levels).

[4] The reagent kit is also purchased from a drug manufacturer and usually requires only simple manipulations such as adding the radioisotope to a vial and shaking.

over until they have decayed beyond usefulness at which time they are often returned to the manufacturer.

Considerations of radiation safety in nuclear medicine can be divided into three areas of concern (1) the radiation safety of the workers (2) the radiation safety of the general public and (3) the radiation safety of the patient.

During the production of radioisotopes and during manufacture, distribution, use and disposal, the radiation exposure of workers must be kept within acceptable limits. A recent study of 47 medical institutions indicates that the radiation exposure of medical workers is comparable to that of industrial radiographers and nuclear reactor personnel. The general radiation safety considerations in nuclear medicine are similar to those in the rest of the nuclear industry: (1) training of personnel, (2) adequacy of facilities and equipment, and (3) control of releases of radioactivity. The radiation exposure to workers is in part a function of the quantity of radioactive material handled, which is in turn a function of the number and types of nuclear medical procedures performed. The increase in the use of nuclear medicine over the past 30 years and the trend to shorter half-life radioisotopes has been accompanied by an increase in the exposure to workers. The general public is exposed to the radioactive effluents from the drug and device manufacturers and medical institutions. The extent of this exposure is not known. The BEIR report predicts cumulative patient dose from diagnostic nuclear medicine alone will reach 3.3 million person-rem/year by 1980. This compares to exposure from background radiation of 10 million person-rem/year.

Of major importance to the practice of medicine is the safety and efficacy of drugs and devices with respect to the patient. In nuclear medicine this includes radiation safety. Any drug or device must be shown to be effective in diagnosis or treatment. Harmful side effects (or adverse reactions) must be of lesser significance than the intended effect. The safety and effectiveness of both the drug or device and the associated nuclear medicine procedures, parallel safety and efficacy considerations for non-radioactive drugs and devices. Prior to routine manufacture and use, the safety and efficacy of both radioactive and non-radioactive drugs and devices is established with elaborate programs of animal testing followed by investigational testing in humans. The labeling of the drug or device lists the uses for which the product has been shown to be safe and effective. During manufacture, special precautions are taken to establish and maintain the purity of radioactive and non-radioactive components of the radioactive drugs and devices. The radioisotope purity, chemical purity, sterility and freedom from fever producing substances (pyrogens) is checked through quality control testing of samples from each lot. Most quality control testing is completed before a product is released; however, in the case of ^{99m}Tc and other short half-life radioactive drugs, sterility and pyrogen tests are not completed until after the product is released.

In nuclear medicine, virtually every element in the clinical situation bears in some way on the radiation exposure to the patient. The training of physicians and paramedical personnel (i.e., technicians, nurses, etc.), the quality assurance controls on dosage preparation and the quality assurance controls on the diagnostic and therapeutic instrumentation all

play a role in determining the radiation exposure a patient receives. Key factors in protecting the patient from unnecessary or excessive exposure are (1) the choice of the procedure, drug or device including the desired radiation dose (i.e., the prescription), and (2) assuring the patient receives exactly what was prescribed [i.e.,(a) performing quality control tests (e.g. radioactive assay and checks on the chemical and physical form) to assure that the prescribed dosage of a radioactive drug has been accurately prepared, (b) quality control tests on the diagnostic equipment to insure proper operation (minimizing "retakes"), (c) quality control tests on therapeutic devices (e.g. calibration), (d) patient identification and (e) care in diagnosis and follow up (e.g. removal of all implants, examination for unexpected reactions)].

II. CONTROLS OVER THE PRACTICE OF NUCLEAR MEDICINE

Research in the area of nuclear medicine includes the testing of radioactive drugs and devices (1) in the test tube, (2) in animals and (3) in humans. Testing in humans can be distinguished between testing to study normal body function and the disease process (biomedical research) and testing related to the development of a specific drug or device (clinical medicine). This paper deals only with that research which is identified with the development of a specific drug or device.

Clinical medicine, including clinical medicine research, is the subject of often overlapping controls by a host of governmental and private organizations. Organizations currently involved in regulating nuclear medicine include NRC, the 25 NRC Agreement States, the Food and Drug Administration (FDA/DHEW) the Social Security Administration (SSA/DHEW),

the Environmental Protection Agency (EPA), the Occupation[illegible]afety and Health Administration (OSHA), the Joint Com[illegible]e on Accreditation of Hospitals (JCAH), State health depart[illegible]s, and at least 13 different peer groups, including the Americar Pharmaceutical Association and the American Board of Nuclear Medicine chartered by American Medical Association. The activities of each of these control groups are discussed briefly in the following paragraphs.

NUCLEAR REGULATORY COMMISSION AND THE AGREEMENT STATES

The NRC and the Agreement States regulate the manufacture, distribution and clinical use of byproduct, source and special nuclear material in nuclear medicine. NRC regulates virtually all aspects of the radiation safety of the workers and the general public and certain aspects of the safety and efficacy with respect to the patient. For many years the AEC regulated the safety and efficacy of radioactive drugs and devices with respect to the patient (in consultation with their Advisory Committee on the Medical Uses of Radioisotopes) because the FDA exempted those radioactive drugs controlled by the AEC and radioactive devices were not regulated by the FDA. In 1974 the FDA announced its intention to terminate the exemption for AEC controlled drugs and the AEC withdrew from regulating the safety and efficacy of radioactive drugs. The NRC continues to evaluate the safety and efficacy with respect to the patient of certain radioactive devices, for example, bone mineral analyzers, Pu-238 pacemakers and brachytherapy sources. The NRC does not regulate naturally occurring and accelerator-produced radioactive material (NARM); however, the Agreement States (and most non-agreement states) do regulate NARM. For nuclear medicine, licenses are issued to manufacturers, pharmacies, medical institutions, and individual physicians. NRC licensees are inspected on a scheduled sampling basis for compliance with NRC regulations and license conditions.

FOOD AND DRUG ADMIN[illegible]ATION (FDA)

The Pure Food Drug and Cosmetic Act of 1938 established the authority for FDA to regulate the safety of drugs offered for interstate commerce through controlling the product labeling. Legislative amendments in 1962 gave the FDA tighter control over drug safety and introduced controls over the efficacy of drugs (to foreclose the marketing of safe, adequately labeled drugs that did not work). The Pure Food, Drug and Cosmetic Act of 1938 (as amended) provided FDA the authority to control the manufacture of drugs, including radioactive drugs, but did not provide authority for FDA to control the use of these drugs. Specifically, FDA has no authority to regulate the way in which a prescription drug is used by a licensed physician (including uses not approved in the labeling). At the same time, FDA requires the manufacturer to carry out investigational programs to establish the safety and efficacy of new drugs and it can take years to substantiate, through clinical trials, a new use for a drug already approved for other uses. Legislative amendments in 1976 gave the FDA authority to regulate medical devices similar to its authority to regulate the safety and efficacy of drugs.

The FDA employs a system of pre-market approval for drugs and pre-market approval, performance standards or general controls for medical devices. The FDA does regulate the use of radioactive drugs and devices during the investigational stage before they are approved for routine use. The FDA discovers violations of its regulation thru periodic inspections, sample analysis and consumer complaints.

SOCIAL SECURITY ADMINISTRATION (SSA)

The SSA controls medical services, including nuclear medicine, by controlling the reimbursement process for Medicare and Medicaid. The SSA sets standards for medical services and then contracts with the individual states for state personnel to conduct periodic inspections of medicare and medicaid providers for compliance with SSA regulations. The Joint Commission on Accreditation of Hospital's accredition is accepted as evidence of satisfying SSA requirements.

ENVIRONMENTAL PROTECTION AGENCY (EPA)

The Environmental Protection Agency regulates the use of radioactive material indirectly through the drinking water standards and directly through Federal Radiation Council guidance. The EPA is contemplating preparing federal guidance to limit patient exposures from nuclear medicine services provided at federal facilities.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

OSHA jurisdiction basically covers the workplace. The Williams-Steiger Occupational Safety and Health Act of 1970 specifically excludes OSHA from jurisdiction in those areas covered by the Atomic Energy Act of 1954 as amended. Thus OSHA, in establishing and enforcing standards to provide safe places of employment, regulates the use of NARM along with other hazardous material but does not regulate the use of byproduct, source, or special nuclear material.

JOINT COMMISSION ON ACCREDITATION OF HOSPITALS (JCAH)

THE JCAH is a private, voluntary organization that (1) establishes standards for the operation of hospitals and other health care facilities and services and (2) conducts periodic survey (inspection) and accreditation programs.

JCAH accreditation is necessary for a hospital to qualify as a teaching facility for physician residency programs. JCAH accreditation also fulfills the SSA requirements for Medicare and Medicaid. JCAH and SSA standards are similar and include specific standards for the delivery of nuclear medicine services.

PEER GROUPS

The peer groups are voluntary organizations that provide various services for their membership, including education, certification, communication, lobbying, and other special interest activities. The major peer groups are the Society of Nuclear Medicine, the American Board of Nuclear Medicine, the American College of Radiology, the American College of Nuclear Medicine, the American College of Nuclear Physicians, the American Society of Clinical Pathology, the American Registry of Radiologic Technologists, the Registry of Medical Technologists, the American Association of Physicists in Medicine, the Health Physics Society, the American Board of Health Physics, the American Pharmaceutical Association, and the American National Standards Institute.

STATE HEALTH DEPARTMENTS

The individual states have police powers to protect the health and safety of their citizens. Each state licenses individual physicians for the practice of medicine within its borders. Each state has pharmacy laws and licenses individual pharmacies (including the "nuclear pharmacies") that prepare drugs for intrastate distribution. Each state licenses pharmacists and nurses, and at least two states license nuclear medicine technologists. Naturally occurring and accelerator produced radioactive material (NARM) are regulated by the NRC Agreement States and most non-agreement states. Regulation of NARM by non-agreement states consists of licensing (5 states) or registration (16 states) and may or may not include inspections.

III. CURRENT STAFF ACTIVITIES CONCERNING NUCLEAR MEDICINE

A. PAPERS CURRENTLY BEFORE THE COMMISSION

(1) SPECIFIC LICENSES FOR INDIVIDUALS AND INSTITUTIONS (SECY-76-383)

The staff has prepared a paper recommending publication of a proposed rule requiring that all medical institutions providing nuclear medicine services be licensed rather than the individual physicians practicing within the institutions. This will ensure that the institution itself is responsible for the radiation safety of all workers, patients and public who may be exposed to radiation from any of its activities. The proposed rule would continue the licensing of individual physicians practicing outside of institutions. A related change would revise the name and function of the presently required institutional committee from a "medical isotopes committee" to a "radiation safety committee".

(2) SPECIFIC LICENSES FROM HUMAN USE OF BYPRODUCT MATERIAL IN SEALED SOURCES (SECY-76-420)

The staff has prepared a paper recommending the publication of a rule that would require the periodic calibration and checking of teletherapy devices. The rule would also require that the person performing the calibration meet minimum training requirements.

B. PAPERS IN FINAL STAGES OF PREPARATION

(1) Pu-238 IN PACEMAKERS

The Final Environmental Statement for the use of Pu-238 in cardiac pacemakers was issued July 23, 1976. The staff is developing a proposed rule to establish general licenses for the implantation and possession by the patient of cardiac pacemakers using Pu-238 power sour

(2) DELETION OF DIAGNOSTIC PROCEDURES FOR GROUPS I, II AND III

The staff is developing a proposed rule that would delete the specification of the diagnostic procedures for the radionuclides listed in Groups I, II, and III of the group medical licenses. Section 35.100 lists groups of medical uses of radioisotopes that have similar requirements for user training and experience, facilities and equipment, and radiation safety procedures. Deleting the diagnostic procedures from the first three § 35.100 Groups will be a step toward deregulating nuclear medicine.

C. PAPERS UNDER STAFF CONSIDERATION

(1) MISADMINISTRATION REPORTING REQUIREMENT

In 1973 the AEC published proposed amendments to its regulations (SECY-R 621) that would (1) require a physician to report to the Commission and to the patient misadministrations of byproduct material, (2) define the duties that could be delegated by the physician to paramedical personnel, and (3) require the appropriate training of paramedical personnel. Miadministration was defined as the administration of a radioactive drug, or radiation from a source (1) other than the one intended, (2) to the wrong patient, or (3) outside of the intended dose range prescribed by the physician or by a route of administration other than intended by the physician. The proposed rule was based on a 1972 General Accounting Office (GAO) recommendation that in turn was based on GAO's review of the AEC's investigations of twelve instances of misadministrations of radioactive material (involving 20 patients) between 1961 and 1972. The staff is developing a new paper to recommend appropritate action on the proposed rule.

(2) PETITIONS

There is a petition under consideration that requests NRC to add a new radioisotope (^{75}Se) to the general license for the use of specific types of byproduct material for *in vitro* clinical tests in §31.11. There is a second petition under consideration that requests NRC to add a calibration source (mixed ^{129}I and ^{241}Am) to the radioisotopes permitted under the general license in §31.11.

(3) ALARA GUIDE FOR MEDICAL INSTITUTIONS

The staff is preparing a guide for medical institutions to aid them in implementing the 10 CFR Part 20 requirements to keep radiation exposures as low as reasonably achievable, economic and social considerations being taken into account (ALARA).

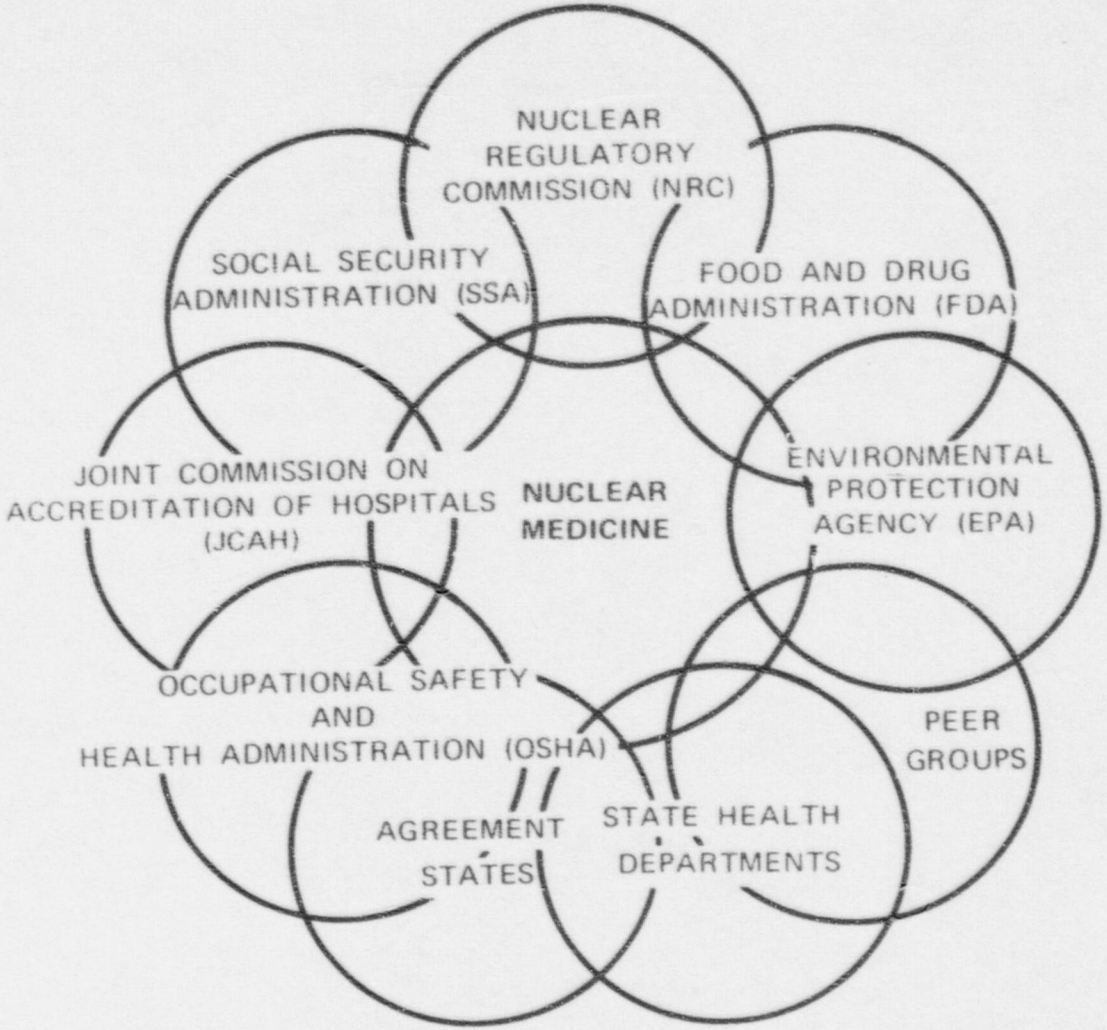
STATE REGULATION OF NARM

AGREEMENT STATES[1]	LICENSING STATES[2]	REGISTRATION STATES	OTHER STATES (and territories)
Alabama	Illinois	Alaska	Delaware issues permit
Arizona	Michigan	Connecticut	District of Columbia registers radium
Arkansas	New Jersey	Hawaii	Iowa no program
California	Pennsylvania	Indiana	Montana registers radium
Colorado	Virginia	Maine	Puerto Rico no program
Florida		Massachusettes	Rhode Island no program
Georgia		Minnesota	Virgin Islands no program
Idaho		Missouri	
Kansas		Ohio	
Kentucky		Oklahoma	
Louisiana		South Dakota	
Maryland		Utah	
Mississipoi		Vermont	
Nebraska		West Virginia	
Nevada		Wisconsin	
New Hampshire		Wyoming	
New Mexico			
New York			
North Carolina			
North Dakota			
Oregon			
South Carolina			
Tennessee			
Texas			
Washington			

[1] Licenses agreement material and NARM

[2] Licenses NARM only

GROUPS CONTROLLING NUCLEAR MEDICINE



NUCLEAR MEDICINE

APPLICATION OF NUCLEAR SCIENCE AND RELATED TECHNOLOGY TO STUDY, DIAGNOSIS AND TREATMENT OF DISEASE. INCLUDES BIOMEDICAL RESEARCH AND CLINICAL MEDICINE

SOME HISTORICAL NOTES ON LICENSING NUCLEAR MEDICINE BY AEC-NRC

1946 – AEC ESTABLISHED; 1st SHIPMENT OF ^{14}C FOR CANCER RESEARCH AUG 2nd; 38 INSTITUTIONS "AUTHORIZED TO PROCURE" RADIOISOTOPES FOR MEDICAL USE.

1948 – ADVISORY COMMITTEE ON ISOTOPES DISTRIBUTION SUBCOMMITTEE ON HUMAN USES FORMED; AEC-SPONSORED TRAINING COURSE IN RADIOISOTOPE TECHNIQUES OPENED AT ORINS.

1950 – AEC INITIATED COOPERATIVE VISITATION WITH STATE HEALTH DEPARTMENTS TO RADIOISOTOPE USERS.
– CRITERIA FOR "BROAD LICENSES" AND PHYSICIANS FOR PRIVATE PRACTICE.

1951 – FDA ACCEPTED FIRST EFFECTIVE NEW DRUG CONTAINING RADIOISOTOPES.

1953 – AEC PUBLISHED CRITERIA FOR HUMAN USE OF RADIOISOTOPES IN F.R.

1954 – 870 INSTITUTIONS AUTHORIZED FOR MEDICAL USE.

1956 – "AUTHORIZATIONS" CONVERTED TO LICENSES UNDER REVISED ACT OF 1954.

1958 – PHYSICIAN CLINICAL TRAINING COURSE OPENED AT ORINS; RESTRUCTURED IN 1962; 1028 PHYSICIANS TRAINED TO DATE.

1962 – FIRST STATE (KENTUCKY) ENTERED INTO A SECTION 274 AGREEMENT WITH AEC.

1963 – FDA EXEMPTED THOSE RADIOACTIVE DRUGS CONTROLLED BY AEC.

HISTORICAL NOTES CONT'D

1965 – ADOPTION OF THE MEDICAL GENERAL LICENSE (3,820 REGISTERED BY NRC TO DATE).

1967 – GROUP LICENSING ADOPTED.

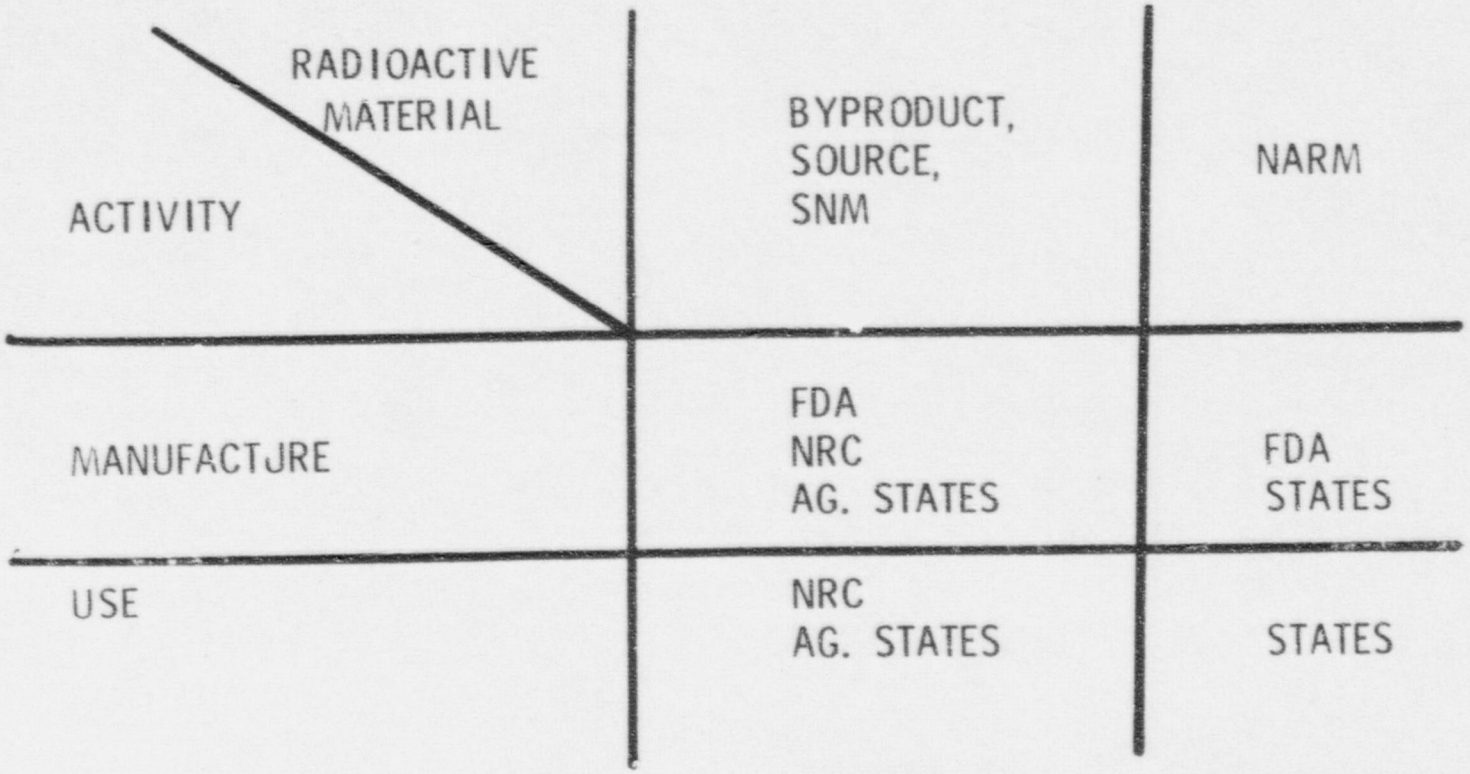
1971 – AMERICAN BOARD OF NUCLEAR MEDICINE BEGINS CERTIFYING PHYSICIANS 2,200 PHYSICIANS HAVE BEEN CERTIFIED TO DATE.

1972 – BEIR REPORT PREDICTS CUMULATIVE PATIENT DOSE FROM DIAGNOSTIC NUCLEAR MEDICINE ALONE TO REACH 3.3 MILLION PERSON-REM/YEAR BY 1980 (VS 10 MILLION PERSON-REM/YEAR FROM BACKGROUND RADIATION).

1973 – IN F.R. FDA & AEC STATED THAT FDA REGULATES THE SAFETY AND EFFICACY OF RADIOACTIVE DRUGS WITH RESPECT TO THE PATIENT AND THE AEC REGULATES THE RADIATION SAFETY OF EMPLOYEES AND PUBLIC.

1976 – THE FDA TERMINATED THE EXEMPTION FOR RADIOACTIVE DRUGS EFFECTIVE AUG. 20;
- THE MEDICAL DEVICE ACT SIGNED MAY 28;
- 2210 NRC AND 2997 AGREEMENT STATE MEDICAL LICENSEES; (EXCLUDING GENERAL MEDICAL LICENSEES).
- 30 MILLION NUCLEAR MEDICINE PROCEDURES/YEAR (DIAGNOSTIC AND THERAPEUTIC);
- 1.6 BILLION DOLLARS/YEAR PAID BY CONSUMER FOR NUCLEAR MEDICINE SERVICES.

PRINCIPAL REGULATORY AUTHORITY FOR NUCLEAR MEDICINE



GROUPS EXERCISING CONTROL OVER NUCLEAR MEDICINE

NUCLEAR REGULATORY COMMISSION (NRC)

FOOD AND DRUG ADMINISTRATION (FDA)

SOCIAL SECURITY ADMINISTRATION (SSA)

ENVIRONMENTAL PROTECTION AGENCY (EPA)

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

JOINT COMMISSION ON ACCREDITATION OF HOSPITALS (JCAH)

PEER GROUPS

(NRC) AGREEMENT STATES

STATE HEALTH DEPARTMENTS

FOOD AND DRUG ADMINISTRATION (DHEW)

BUREAU OF DRUGS

BUREAU OF BIOLOGICS

BUREAU OF MEDICAL DEVICES

BUREAU OF RADIOLOGICAL HEALTH

EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS

SOCIAL SECURITY ADMINISTRATION

BASIS OF CONTROL

MEDICARE & MEDICAID REIMBURSEMENT

HOW EFFECTED

STANDARDS PUBLISHED IN THE FEDERAL REGISTER

INSPECTIONS PERFORMED BY STATE HEALTH PERSONNEL UNDER SSA CONTRACT

JOINT COMMISSION ON ACCREDITATION OF HOSPITALS (JCAH) INSPECTION AND ACCREDITATION ACCEPTED AS COMPLIANCE WITH SSA REGULATIONS

STATE CONTROLS

STATE HEALTH DEPARTMENT – POLICE POWERS (HEALTH AND SAFETY OF CITIZENS)
PHYSICIAN LICENSING
PARAMEDICAL LICENSING
PHARMACY LICENSING
PHARMACIST LICENSING
REGULATE USE OF NARM *

AGREEMENT STATES – NRC AGREEMENT TO REGULATE BYPRODUCT, SOURCE AND SNM

* NATURALLY OCCURRING AND ACCELERATOR PRODUCED RADIOACTIVE MATERIAL (NARM)

PEER GROUPS

SOCIETY OF NUCLEAR MEDICINE
AMERICAN BOARD OF NUCLEAR MEDICINE
AMERICAN COLLEGE OF RADIOLOGY
AMERICAN SOCIETY OF CLINICAL PATHOLOGY
AMERICAN COLLEGE OF NUCLEAR PHYSICIANS
AMERICAN COLLEGE OF NUCLEAR MEDICINE
AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS
REGISTRY OF MEDICAL TECHNOLOGISTS
AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE
HEALTH PHYSICS SOCIETY
AMERICAN BOARD OF HEALTH PHYSICS
AMERICAN PHARMACEUTICAL ASSOCIATION
AMERICAN NATIONAL STANDARDS INSTITUTE

COMPARISON OF CONTROLS

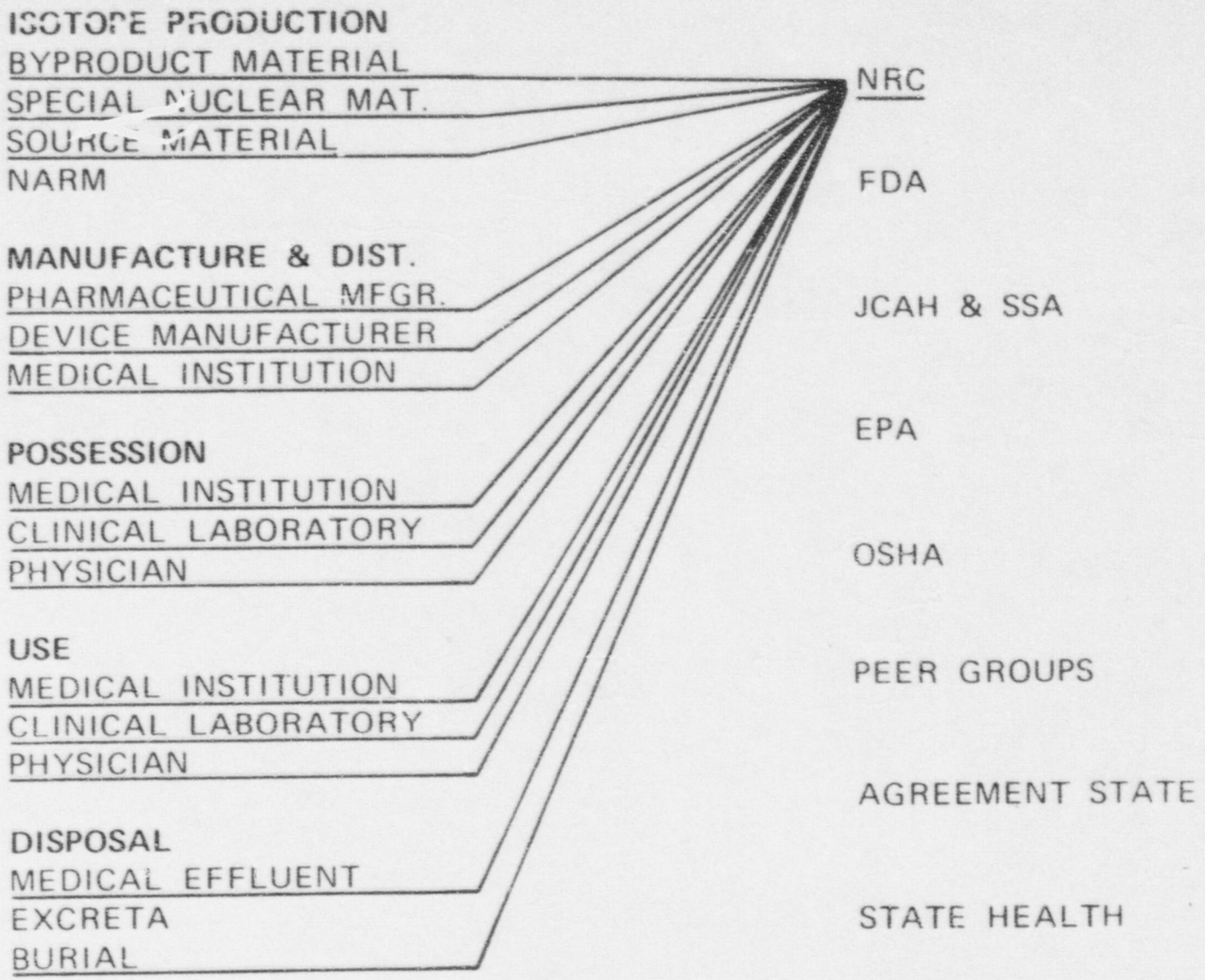
	NRC	FDA	EPA	OSHA	PEER GROUP	JCAH	SSA	AGREEMENT STATES	STATE HEALTH
AUTHORITY	Federal Statute	Federal Statute	Federal Statute	Federal Statute	Charter (Voluntary)	Charter (Voluntary)	Federal Statute	State Statute NRC Agreement	State Statute (Police Powers)
STANDARDS & REGULATIONS	CFR	CFR	CFR	CFR	Published Criteria	Published Criteria	CFR	State Regulation	State Regulation
LICENSING	Prior Approval	Prior Approval	(none)	(none)	Certification	Accreditation	Certification	Prior Approval	Prior Approval (licensing board)
INSPECTION	Scheduled Special	Scheduled Special	(none)	Scheduled Special	(none)	Announced	Random	Scheduled Special	Scheduled Special
ENFORCEMENT	Fines Loss of License Other	Felony Fines Seizure Loss of NDA	Fines	Fines	Loss of Certification	Loss of Accreditation	Funds	Fines Loss of License	Loss of medical license

WHAT IS NUCLEAR MEDICINE? WHO IS INVOLVED IN ITS REGULATION?

	NRC	FDA	EPA	OSHA	PEER GROUP	JCAH	SSA	AGREEMENT STATE	STATE HEALTH
I. ISOTOPE PRODUCTION									
A. BYPRODUCT MATERIAL	●	●						●	
B. SOURCE MATERIAL	●	●						●	
C. SPECIAL NUCLEAR MATERIAL	●	●						●	
D. NARM		●		●				●	
II. MANUFACTURE AND DISTRIBUTION									
A. RADIOPHARMACEUTICAL HOUSE				●					
1. LABELING	●	●						●	
2. QUALITY ASSURANCE		●							
3. PACKAGING	●	●						●	
4. TRANSPORTATION	●	●						●	
B. DEVICE MANUFACTURER									
1. TELETHERAPY & BRACHYTHERAPY									
a. SOURCE	●	●						●	●
b. SHIELD, HOLDER, ELECTRO-MECH.	●	●						●	●
c. ASSEMBLY, QUALITY ASSURANCE	●	●						●	●
d. INSTALLATION	●							●	●
2. PACEMAKER									
a. POWER SOURCE	●	●							
b. ASSEMBLY, QUALITY ASSURANCE	●	●							
3. OTHER	●	●		●				●	
C. MEDICAL INSTITUTION									
1. NUCLEAR PHARMACY	●			●				●	●
2. DEVICES	●			●				●	
3. QUALITY ASSURANCE					●				

WHAT IS NUCLEAR MEDICINE? WHO IS INVOLVED IN ITS REGULATION?

	NRC	FDA	EPA	OSHA	PEER GROUP	JCAH	SSA	AGREEMENT STATES	STATE HEALTH
III. POSSESSION & USE									
A. PHYSICIAN									
1. MEDICAL LICENSE (PRACTICE)									•
2. CLINICAL QUALIFICATIONS	•				•	•	•	•	•
3. RADIATION SAFETY QUALIFICATIONS	•				•	•	•	•	•
4. DEVICE CLINICAL QUALIFICATIONS	•	•			•	•	•	•	
B. CLINICAL LABORATORY									
1. TECHNICAL QUALIFICATIONS		•							•
2. RADIATION SAFETY QUALIFICATIONS	•							•	
C. MEDICAL INSTITUTION									
1. FACILITIES	•					•	•	•	•
2. EQUIPMENT									
a. SURVEY INSTUMENTS	•							•	
b. DOSE CALIBRATORS	•				•	•	•	•	
c. DIAGNOSTIC INSTRUMENTS	•				•	•	•	•	
d. TELETHERAPY INSTALLATION	•							•	
e. TELETHERAPY CALIBRATIONS					•	•	•	•	
3. RADIATION SAFETY PROGRAM									
a. WORKERS	•			•				•	
b. PUBLIC	•		•					•	
c. PATIENT	•		•					•	
4. INSTITUTION COMMITTEES									
a. MEDICAL ISOTOPES COMMITTEE	•					•	•	•	
b. RADIOACTIVE DRUG RESEARCH COM		•							
c. DEVICE COMMITTEES		•							
d. EQUIPMENT DISTRIBUTION									•
5. PATIENT SELECTION	•						•		
6. PROCEDURE SELECTION	•						•		
7. DRUG SELECTION							•		
8. DEVICE SELECTION	•						•		
9. SPECIFICATION OF DOSE									
10. PARAMEDICAL QUALIFICATIONS					•	•	•		
11. PHYSICIST QUALIFICATIONS					•	•	•		
12. RSO QUALIFICATIONS	•							•	
13. DIAGNOSIS									
a. INSTRUMENTATION	•	•				•	•		
b. INTERPRETATION							•		
14. TELETHERAPY CALIBRATION (PERIODIC)					•	•		•	
15. ADVERSE REACTIONS		•			•			•	
16. MISADMINISTRATIONS									
17. PATIENT MANAGEMENT	•							•	
18. QUALITY ASSURANCE	•	•			•	•		•	
IV. DISPOSAL									
A. RADIOCHEMICAL EFFLUENT	•		•					•	
B. EXCRETA (SEWAGE)			•						
C. BURIAL	•		•					•	


ISOTOPE PRODUCTION
BYPRODUCT MATERIAL
SPECIAL NUCLEAR MAT.
SOURCE MATERIAL
NARM
MANUFACTURE & DIST.
PHARMACEUTICAL MFGR.
DEVICE MANUFACTURER
MEDICAL INSTITUTION
POSSESSION
MEDICAL INSTITUTION
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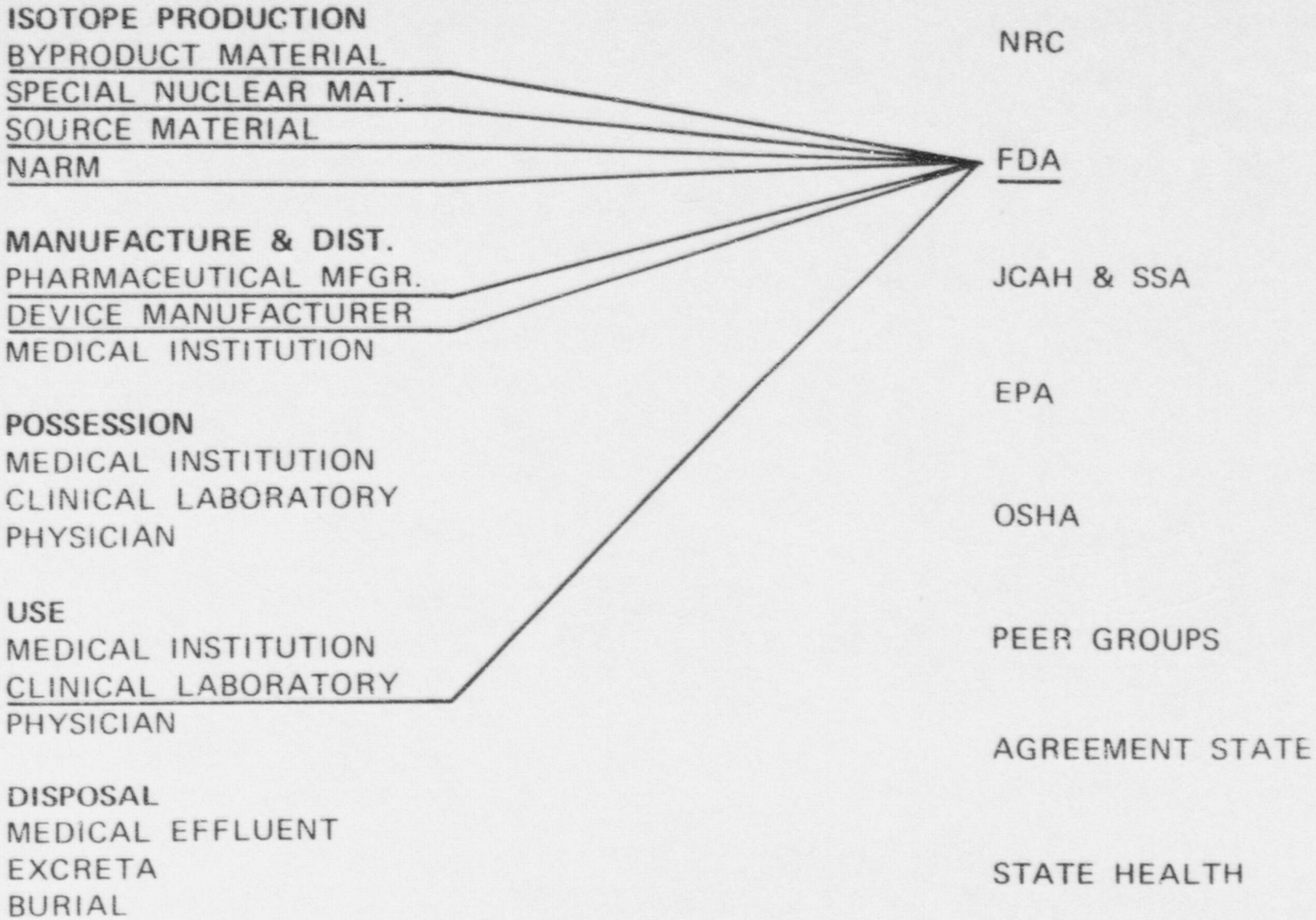
AGREEMENT STATE
STATE HEALTH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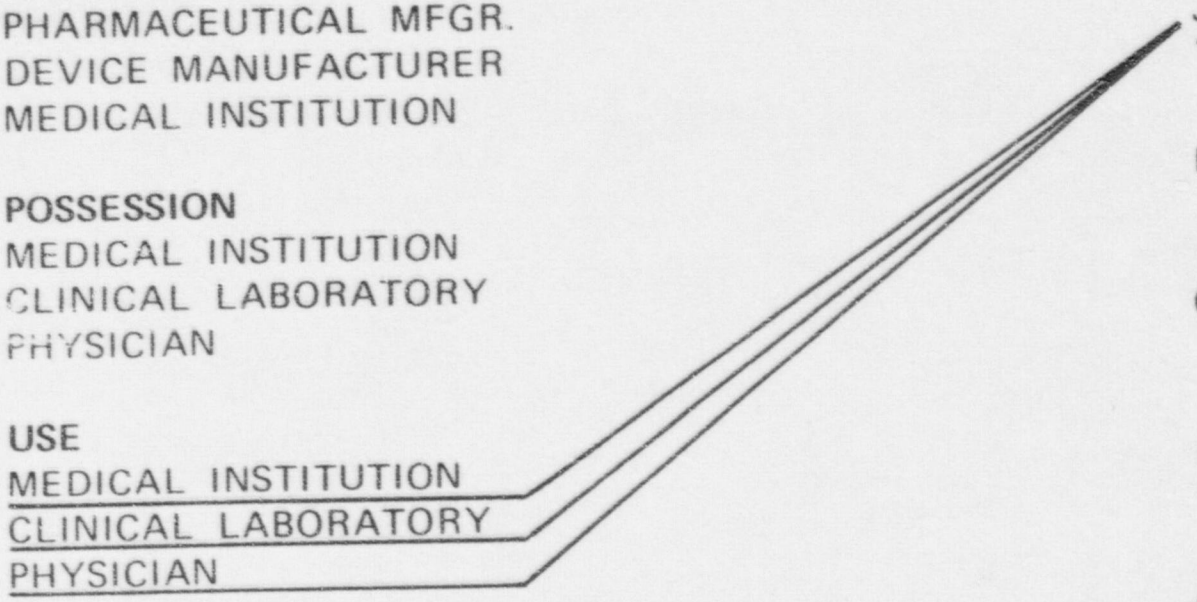

NRC

FDA

JCAH & SSA

EPA

OSHA

PEER GROUPS

AGREEMENT STATE

STATE HEALTH

ISOTOPE PRODUCTION
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SPECIAL NUCLEAR MAT.
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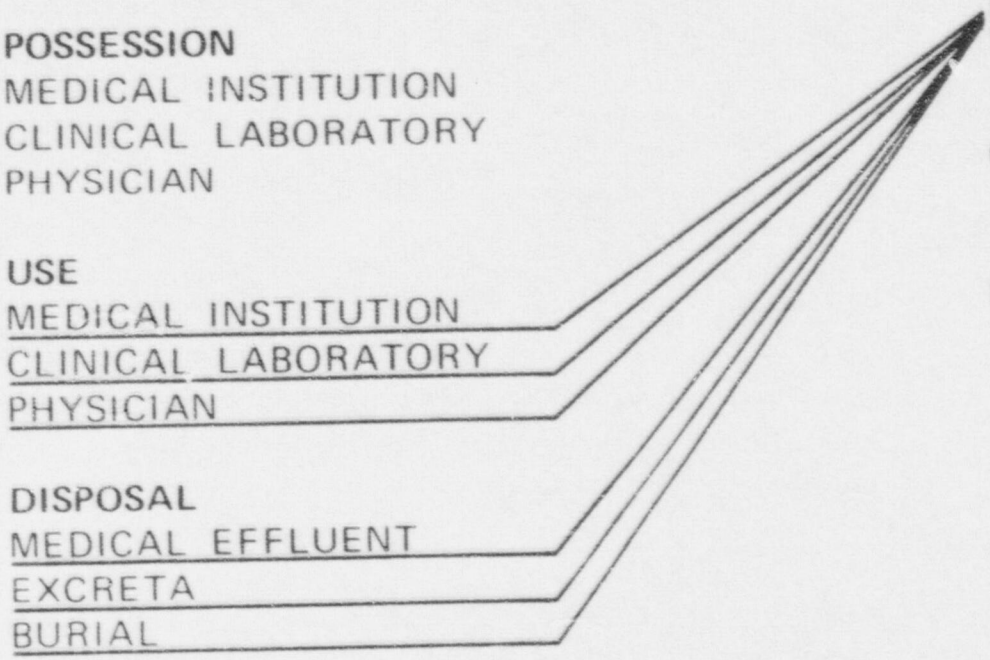

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JCAH & SSA

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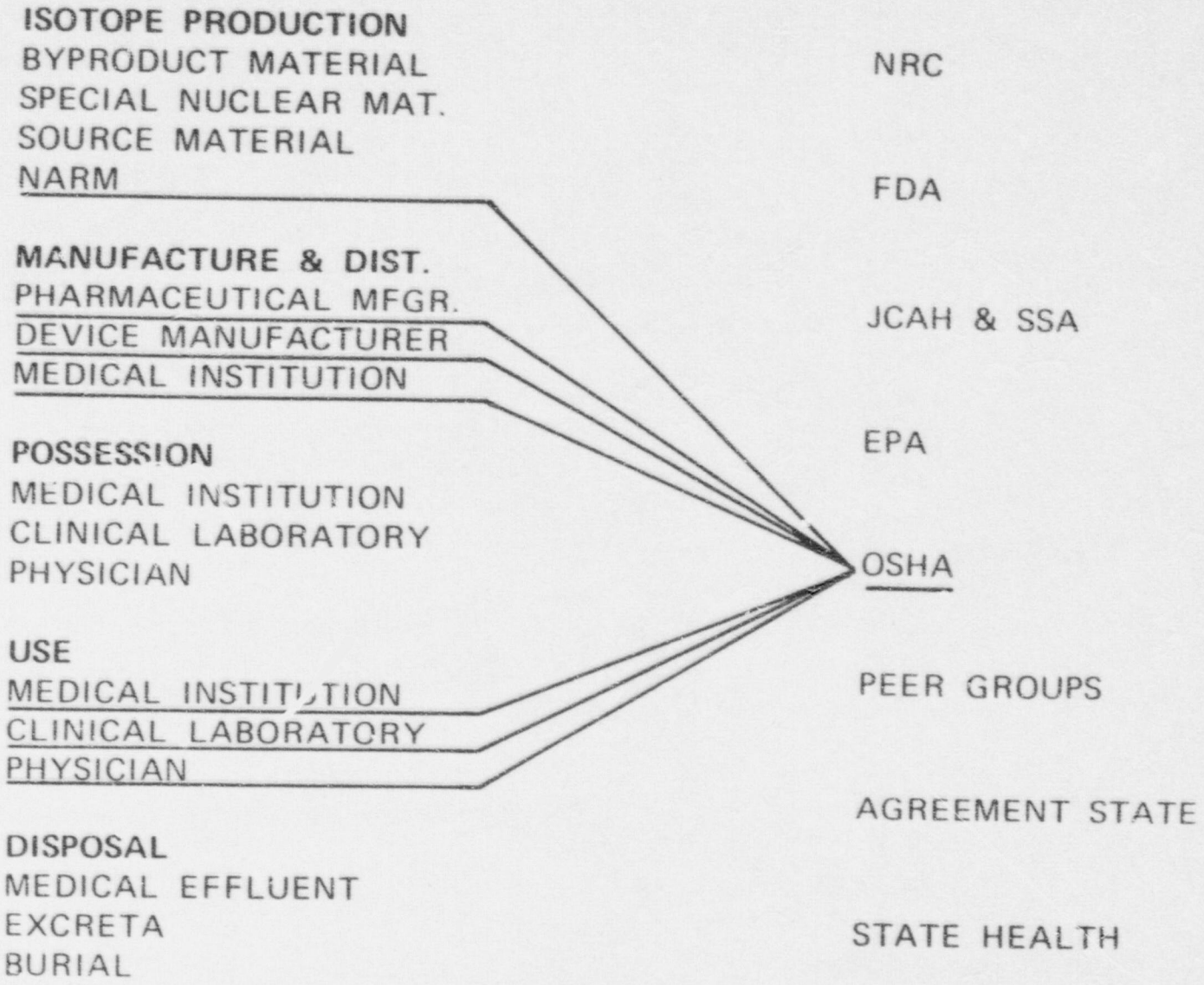
PEER GROUPS

AGREEMENT STATE

STATE HEALTH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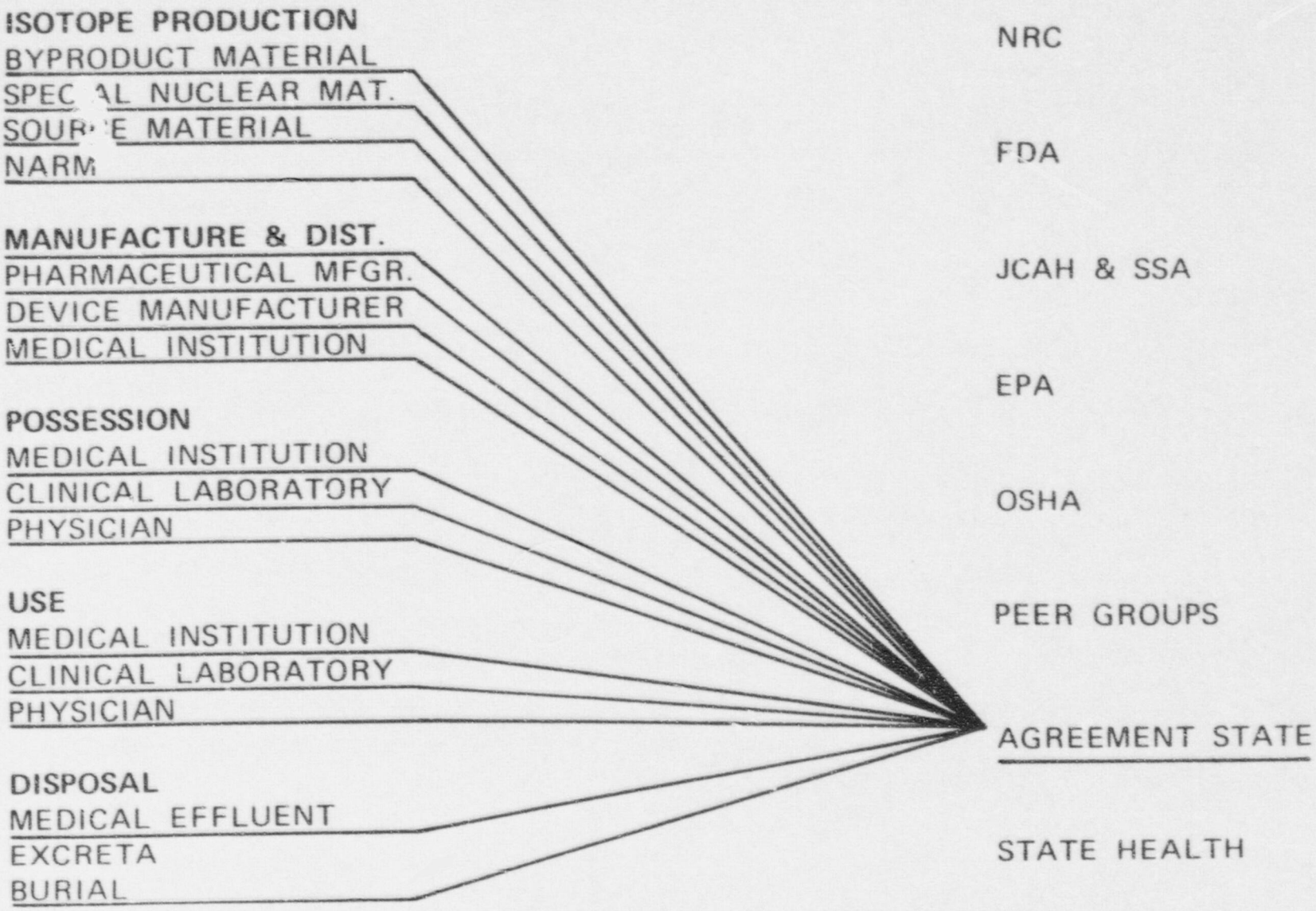
AGREEMENT STAT

STATE HEALTH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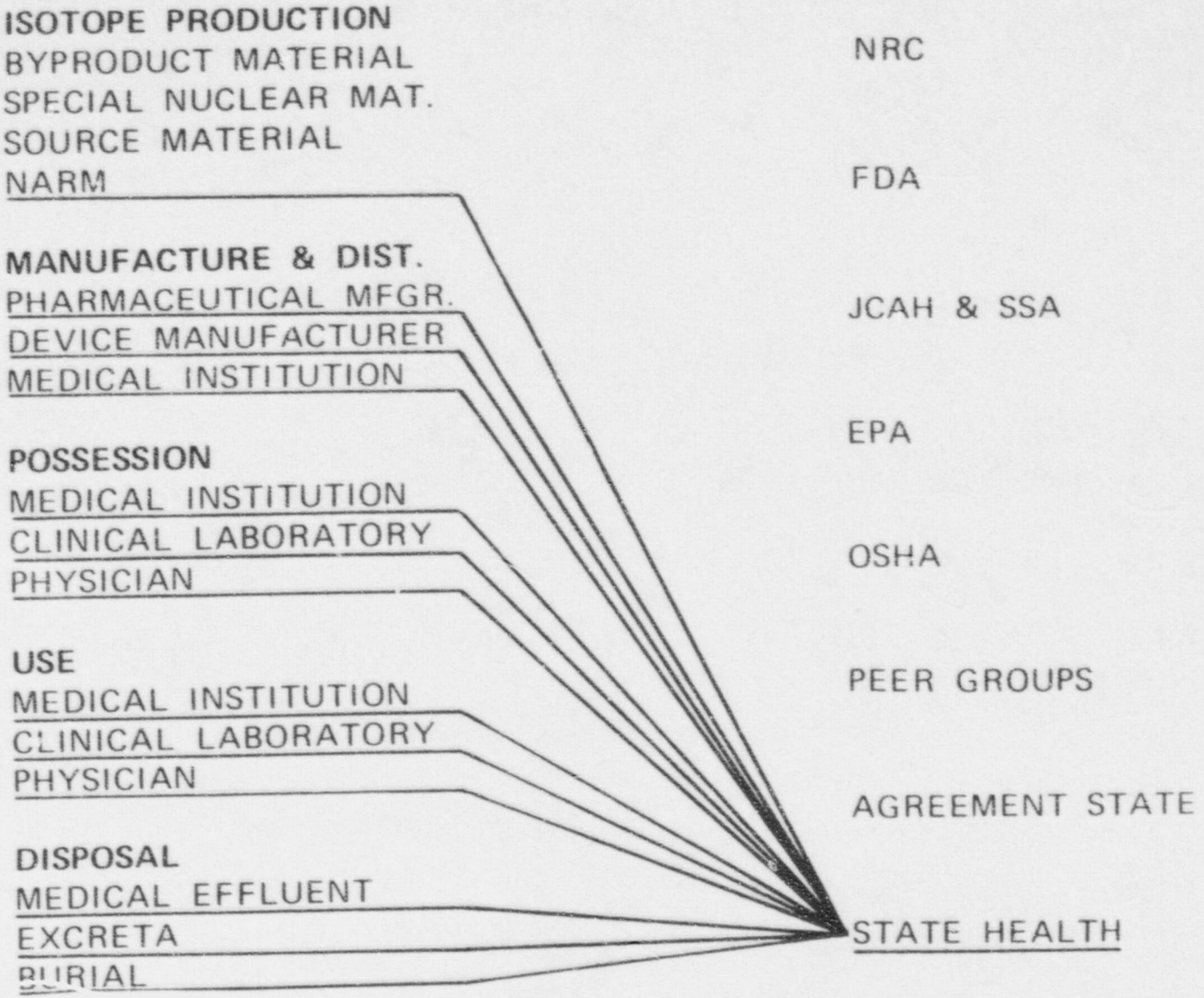
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EPA
OSHA
PEER GROUPS
AGREEMENT STATE
STATE HEALTH

SPECIFIC AREAS OF CONCERN (OTHER THAN NARM)

	NRC	FDA	EPA	OSHA	PEER GROUP	JCAH & SSA	AGREEMENT STATES	STATE HEALTH
I. ISOTOPE PRODUCTION								
A. RADIATION SAFETY OF WORKERS	★			★			★	
B. RADIATION SAFETY OF PUBLIC	★		★				★	
C. SAFETY & EFFICACY FOR PATIENT (RADIATION & OTHER)		★						
II. MANUFACTURE & DISTRIBUTION								
A. RADIATION SAFETY OF WORKERS	★			★			★	
B. RADIATION SAFETY OF PUBLIC	★		★				★	
C. RADIATION SAFETY OF DEVICE	★						★	
D. SAFETY & EFFICACY FOR PATIENT								★
1. LIMITED DISTRIBUTION (IND)	★	★						
2. ROUTINE DISTRIBUTION (NDA)	★	★						
III. POSSESSION & USE								
A. RADIATION SAFETY OF WORKERS	★			★			★	
B. RADIATION SAFETY OF PUBLIC	★		★				★	
C. RADIATION SAFETY OF DEVICE	★						★	
D. SAFETY & EFFICACY FOR PATIENT								
1. INVESTIGATIONAL USE (IND)	★	★	★		★	★		★
2. ROUTINE USE (NDA)	★	★	★		★	★		★
IV. DISPOSAL								
A. RADIATION SAFETY OF WORKERS	★			★			★	
B. RADIATION SAFETY OF PUBLIC	★		★				★	

AREAS OF CONCERN

I. RADIATION SAFETY OF THE WORKERS

II. RADIATION SAFETY OF THE GENERAL PUBLIC

III. RADIATION SAFETY OF THE PATIENT

A. SAFETY AND EFFICACY OF DRUG OR MEDICAL DEVICE WITH RESPECT TO PATIENT

B. PRESCRIPTION
(SELECTION OF PATIENT, PROCEDURE AND DRUG/DEVICE)

C. PATIENT RECEIVES WHAT IS PRESCRIBED
(QUALITY ASSURANCE TESTS AND CALIBRATIONS)

NRC'S INVOLVEMENT BY AREAS OF CONCERN

	RADIATION SAFETY OF WORKERS	RADIATION SAFETY OF PUBLIC	RADIATION SAFETY OF PATIENT		
			SAFETY & EFFICACY	PRESCRIPTION	PATIENT
I. ISOTOPE PRODUCTION					
A. BYPRODUCT MATERIAL	●	●			
B. SOURCE MATERIAL	●	●			
C. SPECIAL NUCLEAR MATERIAL	●	●	●		
D. NARM					
II. MANUFACTURE AND DISTRIBUTION					
A. RADIOPHARMACEUTICAL HOUSE					
1. LABELING	●				
2. QUALITY ASSURANCE					
3. PACKAGING	●	●			
4. TRANSPORTATION	●	●			
B. DEVICE MANUFACTURER					
1. TELETHERAPY & BRACHYTHERAPY					
a. SOURCE	●	●			
b. SHIELD, HOLDER, ELECTRO-MECH.	●	●			
c. ASSEMBLY, QUALITY ASSURANCE	●				
d. INSTALLATION	●	●			
2. PACEMAKER					
a. POWER SOURCE	●	●	●		
b. ASSEMBLY, QUALITY ASSURANCE	●	●	●		
3. OTHER	●	●	●		
C. MEDICAL INSTITUTION					
1. NUCLEAR PHARMACY	●	●			
2. DEVICES	●	●			
3. QUALITY ASSURANCE					

NRC'S INVOLVEMENT BY AREAS OF CONCERN

	RADIATION SAFETY OF WORKERS	RADIATION SAFETY OF PUBLIC	RADIATION SAFETY OF PATIENT		
			SAFETY & EFFICACY	PRESCRIPTION	PATIENT
III POSSESSION & USE					
A. PHYSICIAN					
1. MEDICAL LICENSE (PRACTICE)					
2. CLINICAL QUALIFICATIONS		•		•	•
3. RADIATION SAFETY QUALIFICATIONS	•				
4. DEVICE CLINICAL QUALIFICATIONS				•	
B. CLINICAL LABORATORY					
1. TECHNICAL QUALIFICATIONS					
2. RADIATION SAFETY QUALIFICATIONS	•	•			
C. MEDICAL INSTITUTION					
1. FACILITIES	•	•			
2. EQUIPMENT					
a. SURVEY INSTUMENTS	•	•			
b. DOSE CALIBRATORS					•
c. DIAGNOSTIC INSTRUMENTS				•	•
d. TELETHERAPY INSTALLATION	•	•			
e. TELETHERAPY CALIBRATIONS					
3. RADIATION SAFETY PROGRAM					
a. WORKERS	•				
b. PUBLIC		•			
c. PATIENT					
4. INSTITUTION COMMITTEES					
a. MEDICAL ISOTOPES COMMITTEE	•	•			
b. RADIOACTIVE DRUG RESEARCH COM					
c. DEVICE COMMITTEES					
d. EQUIPMENT DISTRIBUTION					
5. PATIENT SELECTION				•	
6. PROCEDURE SELECTION				•	
7. DRUG SELECTION				•	•
8. DEVICE SELECTION				•	•
9. SPECIFICATION OF DOSE					
10. PARAMEDICAL QUALIFICATIONS					
11. PHYSICIST QUALIFICATIONS					
12. RSO QUALIFICATIONS	•	•			
13. DIAGNOSIS					
a. INSTRUMENTATION					•
b. INTERPRETATION				•	
14. TELETHERAPY CALIBRATION (PERIOD)					
15. ADVERSE REACTIONS					
16. MISADMINISTRATIONS					
17. PATIENT MANAGEMENT	•	•		•	•
18. QUALITY ASSURANCE	•	•		•	•
IV. DISPOSAL					
A. RADIOCHEMICAL EFFLUENT		•			
B. EXCRETA (SEWAGE)					
C. BURIAL		•			

PRESENT NRC CONTROLS

I. & II. RADIATION SAFETY OF WORKERS AND THE GENERAL PUBLIC

Physician Radiation Safety Qualifications
Radiation Safety Officer Radiation Safety Qualifications
Physical Facilities
Survey Instruments
Radiation Safety Program
Institutional Medical Isotopes Committee
Radiopharmaceutical preparation and administration procedures
Administrative controls
Waste Disposal

III. RADIATION SAFETY OF THE PATIENT

A. SAFETY AND EFFICACY OF THE DRUG OR MEDICAL DEVICE WITH RESPECT TO THE PATIENT (Pacemaker efficacy) (brachytherapy)

B. PRESCRIPTION
Physician Clinical Qualifications
Specification of Clinical Procedures in the "Group" Licenses
Review of Diagnostic Instrumentation
Institutional Medical Isotopes Committee

C. ENSURE THAT THE PATIENT RECEIVES WHAT IS PRESCRIBED
Requirement to use "Dose Calibrators" with radioisotope generators and kits; I&E Teletherapy Checks

PAPERS RELATED TO NRC'S INVOLVEMENT IN REGULATING NUCLEAR MEDICINE

1. MISADMINISTRATION REPORTING RULE (Proposed 1973; Staff developed action paper SECY-R 621; Staff developing new paper to recommend disposition of proposed rule)

2. SPECIFIC LICENSES FOR INDIVIDUALS AND INSTITUTIONS SECY-76-383 (Returned to staff 9-9-76)

3. SPECIFIC LICENSES FOR HUMAN USE OF BYPRODUCT MATERIAL IN SEALED SOURCES SECY-76-420 (Returned to staff 9-9-76)

4. Pu-238 IN PACEMAKERS (FES issued 7-23-76; Staff developing a proposed rule for routine use)

5. DELETION OF DIAGNOSTIC PROCEDURES FOR GROUPS I, II, AND III (Proposed rule under development)

HOW ISSUES FIT FUTURE PAPERS

1. SPECIFIC LICENSES FOR HUMAN USES OF BYPRODUCT MATERIAL IN SEALED SOURCES SECY-76-420 (teletherapy calibration)

   III.B. ENSURE THAT THE PATIENT RECEIVES WHAT IS PRESCRIBED.

2. SPECIFIC LICENSES FOR INDIVIDUALS AND INSTITUTIONS SECY-76-383 (physician licensing)

   I. & II. RADIATION SAFETY OF WORKERS AND THE GENERAL PUBLIC.

3. MISADMINISTRATION REPORTING RULE

   III. C. ENSURE THAT THE PATIENT RECEIVES WHAT IS PRESCRIBED.

4. DELETION OF DIAGNOSTIC PROCEDURES FOR GROUPS I, II, III

   III. PRESCRIPTION (SELECTION OF THE PROCEDURE BY THE PHYSICIAN).

5. Pu-238 IN PACEMAKERS

   II. RADIATION SAFETY OF THE GENERAL PUBLIC.

   III. A. SAFETY AND EFFICACY OF THE DRUG OR MEDICAL DEVICE WITH RESPECT TO THE PATIENT.

SCHEDULE TIME FACTORS

ALTERNATIVES	INCREMENTAL TIME FACTOR*
ADVANCED NOTICE OF PROPOSED RULEMAKING	3 MONTHS
PUBLIC MEETING OF NRC MEDICAL ADVISORY COMMITTEE	2 MONTHS
AGREEMENT STATE MEETING	1 WEEK
"PROPOSED" POLICY STATEMENT	3 MONTHS
POLICY STATEMENT (BASIC)	3 MONTHS

* Assumes "Commission Priority" – Certain times can run concurrently.

EXAMPLE SCHEDULE

OCTOBER	ORAL BRIEFING TO IDENTIFY ISSUES FOR COMMISSIONERS	(JOINT NMSS-SD)
DECEMBER	NRC MEDICAL ADVISORY COMMITTEE MEETING (PUBLIC)	(NMSS)
JANUARY	PUBLISH ADVANCED NOTICE OF PROPOSED RULEMAKING IN F.R.	(SD prepared for NMSS)
APRIL	PUBLICATION IN F.R. OF NRC POLICY STATEMENT	(SD prepared for NMSS)