AD 69-2
PDR 008

November 30, 1994

MEMORANDUM TO: Emile Julian, Chief
Docketing and Services Branch, SECY

FROM: Sher Bahadur, Chief
Regulation Development Branch, DRA, RES

SUBJECT: LETTERS TO BE DOCKETED

The Chairman has received a letter from Dr. Carol Marcus concerning the rulemaking entitled "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use" (10 CFR Parts 30, 32, and 35). A copy of her letter is attached. Also attached is a copy of the response signed by Anthony Tse of my staff.

I would appreciate it if you could docket both letters in the file for this rulemaking. Also, please forward a copy of each letter to PDR.

If you have any questions, please contact Anthony Tse at 415-6233.

Attachments:
1. Letter from Dr. Marcus dated 11/4/94
2. Letter signed by Dr. Tse dated 11/22/94

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November 4, 1994

UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

The Honorable Ivan Selin, Chairman
U.S. Nuclear Regulatory Commission
11555 Rockville Pike, 17th Floor
Washington, DC 20555

Re: Draft Final Rule entitled "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Medicine for Medical Use".

Dear Chairman Selin:

I have reviewed the above document and request that you retract and change certain portions which in my opinion are misleading, untrue, dual regulatory, and/or dangerous. As the primary author of this petition by request of the NRC, I feel that NRC's draft final rule is potentially counterproductive, and will create far more problems than it presumes to correct.

The petition was written because NRC's requirements following the 10 CFR Part 35 rewrite effective in 1987 were incompatible with the professional obligations of nuclear medicine physicians and nuclear pharmacists to serve patients in accordance with state medicine and pharmacy law, incompatible with the Food, Drug, and Cosmetic Act and Related Laws, and incompatible with FDA's derivative regulations at 21 CFR. The imminent morbidity and mortality of patients due to NRC's faulty requirements, and NRC's vicious attacks on appropriate medical professionals who bent or broke NRC's faulty requirements in order to effectively care for patients, caused Richard Cunningham of NRC to request this petition in August of 1988.

I do not believe that you, the other Commissioners, or your EDO's Office are aware of the dangerous time bomb cleverly inserted in this draft final rule. Quite simply, your Agency is poised to override 50 State Medicine Laws, 50 State Pharmacy laws, and superregulate the FDA in the areas of byproduct radiopharmaceuticals, byproduct devices, and human research with these products. NRC will regulate the practices of medicine and pharmacy and determine the allowed uses of all FDA-approved byproduct drugs and devices. All Agreement States will have to comply with NRC's usurption of the powers of State Boards of Medicine and Pharmacy and state legislatures. If an Agreement State's Attorney-General finds that NRC's requirements are not compatible with State Law, and the State refuses to comply with NRC's demands, NRC will take back the program, effectively acquiring more licensees to pay NRC's ever-escalating costs for

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its dysfunctional "Medical" Program. After you and Commissioner de Planque are gone, after the National Academy of Sciences-Institute of Medicine (NAS-IOM) Report has been filed in the farthest reaches of NRC's abandoned file cabinets, the specialties of Nuclear Medicine, Nuclear Pharmacy, and portions of Radiation Oncology will continue to be eroded away in this nation by the destructive behavior of your Agency. You must not set the stage to permit this to happen.

After listening to the intelligent presentation made by you to the NAS-IOM, and the elegant one made by Commissioner de Planque, it is obvious that this hostile takeover of medicine and pharmacy is the opposite of what you and Commissioner de Planque intend. I believe that you are being led astray by staff with an agenda in opposition to yours, and that your EDO's Office is naive to this situation.

I will now use NRC's document, "Revised Supporting Statement For Final Rule Entitled 'Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use' (3150-0001, 3150-0010, 3150-0210)", and proceed with my comments.

On p. 2, under "Need for the Collection of Information" for Part 32;72(a)(4), NRC is proposing to require "time of assay" and paperwork verification thereof, and the information that "other regulatory approvals may be required" on the label or leaflet or drug brochure, and verification thereof. NRC states that time of assay is already being printed out on labels. This is false; it is only being done when such information is important. It is done, for example, for Tc-99m-containing radiopharmaceuticals. It is not necessarily being done, for example, for tritium or C-14-containing radiopharmaceuticals. If this is being appropriately done now as NRC states, consistent with State Pharmacy Law or FDA labeling requirements, why is NRC interfering with other regulator's territory, making a requirement for <u>all</u> radiopharmaceuticals, which is scientifically without merit, and then assuming the right to inspect these labels, when added NRC inspection is time-consuming, dual-regulatory, very expensive and absolutely without justification? NRC has failed to document any existing problem with State and FDA control in this area. NRC should have nothing to do with drug labeling, or inspection of drug labeling, at all.

The really dangerous part of this portion is the new requirement that we must print that "other regulatory approvals may be required". NRC's rationalization of this new requirement is to "remind medical use licensees about requirements of other regulatory agencies". Remind <u>us</u>?

Remind NRC perhaps, but not us. We wrote this petition because NRC needed a "reminder" of the requirements of other regulatory agencies. Unlike NRC, we are very well aware of them. Whatever could NRC really mean by this "reminder"? Could it be that NRC intends to make "other requirements", perhaps secret license conditions that are not publicly reviewed, and it is setting the stage for this? Why else is NRC forcing all the nuclear pharmacies in America to reprogram labeling software or otherwise incorporate this bizarre statement on labels? NRC might as well require us to include on the label that we should fasten our seat belts when we drive, just to "remind" us.

It would be most wise if you would remove all labeling requirements from your regulations. He who controls labeling controls drug use, and the practices of medicine and pharmacy, and it is by this mechanism that I believe your staff plans to take power. I will come back to this later, when I discuss NRC's new and creative interpretation of the Atomic Energy Act.

On p. 3 under Section 32.72(c), the NRC is continuing its insidious spread of requirements for written procedures for more and more trivial acts, many of which may be performed by more than one or often many appropriate ways by the knowledgeable professionals who perform these acts. It makes no sense to require professional qualifications for licensure, and then force such knowledgeable professionals to waste large quantities of their valuable time writing unnecessary procedures which may rightfully be varied whenever convenient, advisable, or necessary. The purpose of these procedures is not to protect public health and safety, but to give inspectors something to inspect, something to nitpick on, and something to hold licensees to, even when it makes no sense to do so. It gives NRC something from which to create "violations", and something from which to concoct fines. It is to some extent a ritual of the nuclear navy, but it is inappropriate to let this disorder spread to medicine and pharmacy. Physicians and pharmacists will write procedures as they see fit for those under them, and will interpret these procedures as they see fit as well. Getting back to this particular section, if NRC is licensing nuclear pharmacists who don't know how to use dose calibrators, NRC is criminally negligent. This "procedure mania" is pointless, destructive, and expensive, and must end. Appropriate procedure requirements are already taken care of by healthcare organization management, OSHA, JCAHO, and professional oversight groups. NRC has never presented evidence that these groups' requirements are insufficient to protect public health and safety, nor has NRC ever shown that tomes of procedures have a salutary effect on radiation safety, or that exhaustive NRC reviews of these

procedures are of any value to the nation at all.

It would be wise if NRC removed all requirements for procedures but made certain that its licensees were qualified to handle radioactive material. It would save a huge amount of our money and NRC's mischief. The statements to OMB are inaccurate and need to be redone.

For openers, this rule would apply to all American nuclear pharmacies, not just NRC's licensees. This triples the cost, but the cost estimates are still too low. The paperwork burden could be extraordinary, but the rule is too vague to calculate a credible number. The individual who prepared it is a nuclear engineer, with no qualifications in any aspects of medicine and pharmacy. We require the final (not "draft") regulatory guidance documents for licensees, licensing staff, and inspectors before we can make any meaningful paperwork burden evaluations for OMB. And, it would be best to have your ACMUI and your present and past Visiting Medical Fellows work with the staff on it so that it is realistic and accurate. Your last OMB estimate on the "Quality Management" Rule was too low by tens of millions of dollars, and the true costs are rising even now.

I will now proceed to comment on your 9/27/94 draft rule and statements of consideration.

On p. 1 in NRC's Summary, it sets the requirements for human research. Human research with byproduct material was formally transferred from AEC to FDA in 1975. In the Federal Register article that transferred this responsibility, Commissioner Schmidt of FDA made it clear that NRC would have no participatory role because FDA has to maintain the confidentiality of radiopharmaceutical manufacturers, and because FDA did not feel that NRC had any expertise that FDA required. For twenty years, NRC has rightfully been devoid of any role in human research. When the Uniform Federal Policy for the Protection of Human Subjects was created, NRC was not included, because NRC had no recognized role. When it was published in draft form, in the Federal Register, NRC made no comments, because NRC had no recognized role. Why in the world, after 20 years of effective oversight by FDA, state, and professional bodies, has NRC suddenly decided that it needs to dual regulate this activity? NRC has no contribution to make at all. NRC can only cause problems, interference, and expense. Last February in a document sent by James Taylor to the Commission, it states that NRC inspectors will review the ethical issues of research submissions to Institutional Review Boards. As FDA does this, and as NRC has absolutely no competence in this area, I see nothing but trouble ahead.

I do not believe that there is any evidence of NRC or Agreement State licensees carrying on human research with byproduct material that is not being done under the Federal Policy. If there is, it is already covered by FDA's "safety net" authority. There is only one activity going on today that I know of in which human beings are being subjected to "medical experiments" with byproduct material without informed consent. These are the "medical experiments" being perpetrated by the dangerous, naive dilettantes of NRC on America's patients. Don't you think you ought to stop?

The issue of medical research was covered in the petition because NRC accidentally left all mention of it out of its 1987 Part 35 rewrite. It was NRC's blunder, probably because it had been (rightfully) removed from this activity for so long. NRC had to amend all licenses to include research when licensees wished to perform it. Such paperwork and extra costs were unnecessary. We wanted NRC to put permission to conduct human research back in its regulations. We certainly do not want NRC's inspectors or NRC's opinion along with it.

On p. 2, under "Background", please change the first sentence to read, "In the spring of 1988, representatives of the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) approached Norman McElroy and Richard Cunningham with serious concerns and strong complaints that the Commission's regulations and license conditions prevented nuclear physicians and nuclear pharmacists from efficiently and effectively caring for their patients, and that these licensees were being gleefully victimized by NRC staff for attempting to do so despite NRC's requirements to the contrary". Please change the second sentence to read, "At the suggestion of Mr. Cunningham, the ACNP and SNM submitted a petition for rulemaking in early June, 1989, requesting the Commission to amend its regulations to fully recognize State Boards of Medicine and Pharmacy, the FDA, the USP, and the JCAHO and their guidance, regulatory, inspection, and enforcement roles, and to stop interpreting their requirements or otherwise interfering with these entities". In the second paragraph of this section you might clarify the truth by stating that Mr. McElroy did not participate in the resolution of the petition or the development of this rule because he was fired by Admiral Carr for honestly voicing his opposition to the fraudulent "Quality Management" Rule when asked his opinion by Carr's staff assistant. You might also mention that the NRC staff member who reviewed the petition prior to its formal submittal had limited participation in this final resolution because you made him a scapegoat for the supposed "shortcomings" of the "Medical" Program portrayed in the Cleveland Plain Dealer exposé, and fired him. It is interesting

that you did not fire the NRC staff that contributed many of the distortions to the Cleveland Plain Dealer.

At the bottom of p.3 NRC states that, "Specifically, the petitioners requested that nuclear pharmacists be permitted to ...(2) Compound radiopharmaceuticals whose manufacture and distribution are not regulated by the State or FDA; ...(5) Dispense radiopharmaceuticals that are not regulated by the FDA".

Statement (2) is a purposeful NRC untruth; it appeared in the proposed rule and I pointed out the inaccuracy in my comment letter. To reiterate it is deceitful; the petition stated the opposite. Boards of pharmacy are responsible for this activity, and FDA has "safety net" authority, and the petition so stated this. Kindly see to it that your staff makes the correction. Statement (5) is misleading. The Boards of Pharmacy regulate this, not FDA, but FDA does have "safety net" authority. One might ask why NRC would falsify what the petition asked for. I submit that it wishes to give the false impression that these drugs are uncontrolled in order to take over the activity itself.

In late summer of 1988 Donna Beth Howe told me, then repeated to certain ACNP/SNM leadership, that she wished to regulate the practice of nuclear pharmacy herself at NRC. She has never stopped trying.

In the discussion pertaining to the Immediately Effective Interim Final Rule published in 1990, NRC should be aware that "Medical" Section staff word-smithed it until it was practically useless, led an assault on licensees who applied it, and Hugh Thompson had to step in and gut the reporting and record-keeping requirement in order to stop the NRC abuse.

On p. 5, NRC reprints its 1979 "Medical Policy Statement". The ACMUI finds fault with this policy, and has been trying for several years to change it. In any case, where does even this 1979 Policy cover NRC's intent to dual-regulate other agencies in areas like medical research, medical quality assurance, drug labeling, or drug use? When I read the Policy, just the opposite is implied. NRC logic is severely flawed and I request that you review this carefully and repair it.

On p. 6, NRC covers the comment letters for the proposed rule.

The support for the rule assumed that the practices of medicine and pharmacy would be under State Boards of Medicine and Pharmacy. The original petition, supported by medical and pharmaceutical organizations composed of 310,000 health care professionals, supported this. No one competent is supporting

NRC regulation of drug labeling, drug preparation, or drug use. A couple of years ago, when you and David Kessler exchanged letters, Hugh Thompson and Jim Taylor called me to tell me that NRC was getting completely out of drugs. I was delighted, but skeptical that the NRC staff in the "Medical" Section would comply. Well, I was right. They haven't. Why has your EDO's Office failed to communicate effectively with the staff?

On p.7 and 8, NRC makes an unrespectable case that the caveat for "minimum regulation" in Section 104 of the Atomic Energy Act does not apply to byproduct material, but only to nuclear reactors and special nuclear material. That means that NRC should have "minimal regulation" if I position a patient in a reactor port and irradiate him. NRC should have "minimal regulation" if I decide to have a patient inhale Pu-239 for treatment of lung disease. NRC should have "minimal regulation" if I inject U-235 into a patient to treat a bone marrow disorder. But dare I use virtually harmless Tc-99m for diagnostic purposes, NRC can microregulate every single thing I do? Mr. Chairman, this is preposterous. Section 104 applies to byproduct medical therapy also. Special nuclear material and reactors were for making byproduct material, as opposed to making nuclear weapons, which was a real consideration in 1954. By warning NRC to make "minimum regulation" for the widest amount of effective medical therapy possible, but not mentioning the far safer (10^{-4} factor in radiation dose) medical diagnostic procedures (these existed in 1954), one can even interpret Section 104 to mean that NRC should have no regulation for diagnosis at all. Your office of General Counsel, ever ready to prove that the Atomic Energy Act gives NRC jurisdiction over everything in the universe, is guilty of overstatement to the point of scientific and medical absurdity. This may well be characteristic of some of your lawyers, but I do not think it would look appropriate for the Commission and the EDO's Office to sign off on this. Please alter this section appropriately.

On p.9, the NRC answers the comment that NRC is not competent in the medical or pharmaceutical area, and should not attempt to regulate these activities. NRC claims it has competence by statute, has long experience in regulating medicine, and in recent years has increased its recruitment of personnel who have experience and knowledge either in nuclear medicine or in radiation therapy. In the first place, the Atomic Energy Act does not magically turn incompetence into competence; only lawyers would make such a disgusting argument. Second, NRC certainly has had long experience in regulating medicine, has done so badly and is becoming progressively worse, and should end this activity at long last. Third, the recruitment of personnel

includes only a potpourri of scientists and techs, none of whom are competent in nuclear medicine, nuclear pharmacy, or radiation oncology. A number of them came to work at NRC only after losing their previous jobs. NRC's management, composed of two nuclear physicists and three nuclear engineers, are intelligent men but incompetent in all areas of medicine and pharmacy. None are qualified even in medical physics. Sorry, Mr. Chairman, but NRC's response is poor. Why doesn't NRC just admit its medical and pharmaceutical lack of competence and stick to 10 CFR Part 20 (and fix it)?

On p. 10, NRC also brags about its use of the ACMUI. The ACMUI, once important, has become farcical over the last few years. When the ACMUI voted on the "Quality Management" Rule, the vote was unanimous against the entire mess, with the two physicists abstaining because it was a medical practice issue, and the Chair not voting. Not only did the NRC ignore the ACMUI, it used fraudulent data purposely concocted by a member of the "Medical" Section, even when it was informed of the fraud, and NRC even repeated the fraud in Federal Court. The record of NRC in the "Quality Management" Rule is a complete unethical travesty. In addition, the ACMUI has been trying to get the ACNP/SNM pharmacy petition granted for over five years. The war with "Medical" Section staff and the Office of General Counsel has been vile. The ACMUI has been trying to get an appropriate patient discharge rule for nearly four years. The last NRC attempt was pitiful. As NRC doesn't use the advise of its ACMUI, I suggest NRC leave mention of it out of this document altogether.

On p. 10, NRC states that this duplicative rule is not duplicating regulation by other federal or state agencies. This is not true. If NRC really means it, why doesn't NRC state that no rule, license condition, procedure requirement, or inspection of anything under the jurisdiction of other federal or state agencies will carry any obligation on the part of the licensee? Goodbye everything except 10 CFR Part 20!

On p. 17, NRC states that the Atomic Energy Act gives NRC independent jurisdiction over the labeling of byproduct radiopharmaceuticals, and argues that NRC's labeling requirements only have to do with radiation safety, as though FDA and Board of Pharmacy labeling ignore radiation safety. NRC is not the only agency that recognizes radiation safety; FDA and Boards of Pharmacy certainly do as well. Whom does NRC think regulates radiation safety labeling of non-byproduct radiopharmaceuticals? I do not believe that the Atomic Energy Act gives NRC independent drug labeling authority. NRC might have claimed this responsibility before 1975 when AEC regulated byproduct radiopharmaceuticals. However, in 1975 FDA lifted the exemption

for byproduct drugs and human research with it, and labeling went to FDA as part of its drug responsibility. It was Richard Cunningham who asked FDA to lift the exemption, when he realized that nuclear medicine was growing and that NRC lacked any drug reviewing competence. He was right. Why does NRC want to reverse this 20 years later? Too many staff with nothing important to do and mischief on a few minds?

Let us see what abuses this can lead to. Let us look at the area of byproduct devices, for example. According to Dr. Robert Phillips of CDRH, FDA has approved labeling for Sr-90 eye probes that includes any superficial lesion one can get near. It is published at 21 CFR Part 892.5650 (attached). Yet NRC refuses to permit radiation oncologists to use these probes to treat anything but eyes. NRC is now pressing criminal charges against a radiation oncologist for daring(!) to use this probe to treat superficial facial lesions, which he had successfully treated before with this instrument in Texas. NRC states, although the physician denies it, that the physician tried to "hide" these cases from NRC inspectors. When this physician tried to amend his license to include lesions other than pterygia, NRC refused to honor FDA's labeling and refused to grant the license amendment. NRC also told the physician that the ACMUI reviewed this issue and determined that it was inappropriate to use the Sr-90 eye probe for anything but eyes. However, the truth is that the ACMUI never reviewed this. NRC has also taken away this physician's byproduct license.

Mr. Chairman, please call off your lawyers and enforcement staff. This is shameful abuse of power by NRC. This is what happens when NRC claims "independent labeling authority" from FDA. It is very, very dangerous to physicians and patients. On the bottom of page 17 NRC states that NRC inspectors will not check the label of every container or package of a radioactive drug, but they may conduct spot checks. I can think of little more ridiculous, unnecessary, harassing, expensive, and time-consuming activities than having NRC (!?) inspectors torturing licensees by checking their drug labels. NRC must have a lot of extra inspectors with nothing useful to do.

On p. 18, NRC offers the weak rationalization that increased labeling requirements "are necessary because they serve as warnings to individuals who are not authorized to use the byproduct material". That is pure NRC balderdash. Unauthorized individuals do not have access to radioactive drugs. My janitors can't even read English; it is enough for them to learn to avoid anything with a radiation sign. They don't get near radioactive drugs. What nonsense! NRC staff is still trying to delude NRC management and leadership into overlooking a setup for the

hostile takeover of drugs. Don't be cuckolded. End this, please.

On p. 19, the NRC continues to threaten to withhold the professional rights required by this rule by stating that it will first judge the authorized user's "character". In the first place, the characters of NRC are not capable of judging our character. Second, the character of physicians and pharmacists is determined by State Boards of Medicine and Pharmacy, in keeping with state law. Physicians and pharmacists with unacceptable character have their licenses removed. Patients are not exposed to care from half-licensed "bad characters". NRC has no statutory authority here; it may request the attention of Boards of Pharmacy and Medicine, but NRC is so abusive with its "character" determinations that it is a danger to professionals and patients. I request that you remove this "character" determination from this rulemaking. As every inspection results in unacceptable NRC "violations", we are all of "bad character" by NRC's definition. We are not interested in NRC's opinion of our "character". Please end this dangerous precedent and and let us practice medicine and pharmacy effectively and efficiently, in service to our patients.

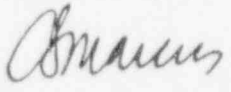
On p. 24, NRC states that it "solicited public comment on the number and type of research activities which would not be funded by another Federal Agency which has adopted the Federal Policy and which would require a license amendment under the proposed rule. No comments on the number and type of such research activities were received". That is not true. A large pharmaceutical company submitted a letter regarding research that it funds for research and development purposes. When I was your advisor and consultant, I explained that many of our research projects are not funded by federal agencies. NRC is either unable to listen, or is misleading the public. NRC has not been involved in our research activities for two decades. Please keep it that way.

On p. 50, NRC announces that this rulemaking will involve level 1 or 2 compatibility for all significant portions. I object to this because this interferes with State Medicine and Pharmacy Law, which differs to some extent from state to state. NRC should bow to these State Laws, not seek to override them. Given the flaws in this proposed regulatory construct, I don't know any intelligent Agreement State that would want to touch much of this. For over three years, California has upheld the determination that nuclear pharmacists practice pharmacy according to State Pharmacy Law, Nuclear Medicine physicians practice medicine according to State Medicine Law, research is FDA's business, and Radiological Health takes care of Radiologic

Health. It is cheap to run, the medical professionals are pleased, and patients get efficient and effective medical care. We have higher requirements for authorized user physicians than does NRC, higher requirements for technologists than does NRC, and de facto higher requirements for physicists than NRC, which will probably be law next year. We account for 20% of the nuclear medicine procedures of the United States. NRC, while having 1/3 of the nation's licensees, probably accounts for no more than 25% of procedures. Yet California, for much less money, has better quality care and proportionately fewer mistakes than NRC licensees. It must be that we are much better than NRC. Mr. Chairman, maybe you need to come out and discover why we have better quality medicine, at a cheaper price, than NRC licensees, why California licensees support their Radiologic Health Branch, and why NRC licensees hate NRC. Please end this compatibility requirement. The parts that are good will be adopted by Agreement States. The parts that are not will be left to wither and die.

Thank you for your attention and consideration. I recommend that you see to these changes personally, as your management has once again not "done its homework".

Sincerely,



Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Professor of Radiological Sciences
UCLA

cc: Commissioner E. Gail de Planque
Commissioner Kenneth Rodgers
Hugh Thompson, Deputy EDO
James Taylor, EDO
Robert Bernero
Carl Paperiello, Ph.D
Barry Siegel, M.D., Chair, ACMUI
Secretary, USNRC
Myron Pollycove, M.D.

CSM:sfd

RANDOM SAMPLES

edited by CONSTANCE HOLDEN

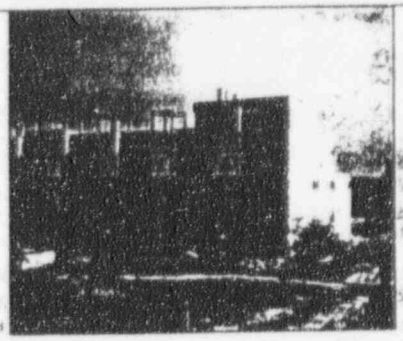
New Blood Charges In Paris

France's contaminated blood scandal has entered a dramatic new phase. Several scientists and politicians have been charged with "complicity in poisoning" for their role in allowing the national blood supply to go untested for HIV. Last week, cell biologist François Gros—a former scientific counselor to the prime minister and one of the country's best-known scientists—and physician Claude Weisselberg, a former adviser to the health ministry, were added to the roster of the accused. And late last month, former French Prime Minister Laurent Fabius and two of his former ministers were called before a judge to answer similar charges, stemming from decisions they allegedly made in the mid-1980s to delay universal testing of blood supplies for the AIDS virus.

This new round of charges greatly extends the scope of the affair, which until now had been limited to the provision of untreated blood products to French hemophiliacs. Four physicians were convicted in that episode, and two were sent to prison (*Science*, 12 August, p. 859).

The focus now is on the critical period between May and July 1985, when the French government allegedly kept an HIV antibody test manufactured by the American firm Abbott off the market while waiting for the French firm Diagnostics Pasteur to get its own version ready. During this time, several hundred people could have received tainted blood transfusions.

The French press has long treated as a "smoking gun" the minutes of a May 1985 meeting of government AIDS advisers, presided over by Gros, in which participants discussed the threat to French commercial interests posed by the American test. But Jean-Baptiste Brunet, one of a small group of doctors who urged early HIV testing and is now director of the European Center for the Epidemiological Surveillance of AIDS in Paris, says technical and logistical problems were also factors in the delay. "Could [testing] have begun earlier?" asks Brunet. "Maybe so. ... But to charge someone with poisoning means accusing them squarely of murder." A special magistrate will now conduct an investigation to assess the charges and decide whether the accused should stand trial.



Building biology. Almost-completed permanent premises of ICGEB New Delhi branch at Jawaharlal Nehru University.

World Biology Center

Last week marked the official opening of an international research center in Trieste, Italy, whose purpose is to strengthen the research capacity of developing countries. The International Center for Genetic Engineering and Biotechnology (ICGEB), which started under the aegis of the United Nations Industrial Development Organization (UNIDO), now has enough support to strike out on its own. Its goal, says director Arturo Falaschi, is to train scientists from the developing world who will work at ICGEB on subjects related to industrial and agricultural development and then bring their skills back home.

ICGEB has two lab complexes: a 140-person institute in Trieste and one in New Delhi that houses around 70 scientists. There are also some 20 affiliated research groups in ICGEB's member countries—32 nations, mostly from the developing world, but also Italy and several eastern European countries.

The Trieste and New Delhi labs have been operating for several years, but until now ICGEB was governed by UNIDO, whose full membership had to approve all major decisions. The breakthrough came in February, when the treaty establishing the center finally got the 24 ratifications necessary for independence. Falaschi says the center's new status will make it much easier to win grants from industry and from bodies like the European Union. And it will have more financial security. Currently, ICGEB's $12-million-a-year budget comes from the governments of India and Italy. By 1999, this should grow to around $15 million, with ICGEB's other member states contributing a total of $5 million a year. Falaschi hopes eventually to get developed countries on board as well.

$86 Million for Biology Classes

The Howard Hughes Medical Institute (HHMI) has awarded what it calls "the largest series of grants by a private organization in U.S. history."

On 4 October HHMI announced that $86 million in 4-year grants of between $1 million and $2 million each is being awarded to 62 doctorate-granting institutions to improve undergraduate biology education. The awards are part of a program started in 1988 which has so far committed $290 million to 213 colleges and universities. The money is for undergraduate research, including drawing more females and minorities into science, equipment and laboratories, and science education activities with local elementary and high schools.

HHMI claims that the program has enabled the appointment of new faculty members, supported the development of thousands of new courses, and enhanced science education for 37,000 precollege students. The institute is especially proud of the University of Arizona, says HHMI spokesperson David Jarmul. With a 1989 HHMI grant of $1.5 million, it set up an undergraduate research program that by its third year in operation drew some 114 students. Michael Wells, head of the university's biochemistry department, adds that the last 5 years have seen "a 500% increase [from about 12 to 75 a year] in the number of students going on to graduate school as a result of this program." Adds Wells: "With a multi-year research experience, students become very, very good in the lab," and that encourages them to apply to grad school.

Next-Generation Patch?

Our skin, usually a barrier to invaders from the world outside, may prove to be a valuable point of entry for therapeutic genes. A team of biologists at the State University of New York (SUNY)–Stony Brook, led by Lorne Taichman, reports that it has successfully delivered a genetically engineered protein into the bloodstream of mice by grafting human skin cells containing a gene for that protein.

The SUNY group reports in the October issue of *Human Gene Therapy* that their mice expressed a recombinant version of apolipoprotein (apo-E), a protein that ferries cholesterol out of the bloodstream. Although apo-E is naturally secreted by human skin, getting more of it into the bloodstream could help stem cholesterol buildup as happens in atherosclerosis, says Elizabeth Fenjves, the paper's first author.

But it's the larger implications that are "exciting," she says. "If you had a disease where a protein was missing, theoretically you could take a small skin biopsy from the patient, grow those cells in culture, insert the gene ... and graft these cells back onto the patient. Now his own skin cells

) Radiographic head holder.

lentification. A radiographic lder is a device intended to po- ie patient's head during a radi- c procedure.

Classification. Class I. The s exempt from the premarket tion procedures in Subpart E 807. The device is exempt from rent good manufacturing prac- ulations in Part 820, with the on of § 820.180, with respect to requirements concerning and § 820.198, with respect to nt files.

0 Radiologic quality assurance ument.

entification. A radiologic qual- rance instrument is a device in- for medical purposes to meas- ysical characteristic associated other radiologic device.

Classification. Class I. The s exempt from the premarket tion procedures in Subpart E 807. The device is exempt from rent good manufacturing prac- ulations in Part 820, with the on of § 820.180, with respect to requirements concerning and § 820.198, with respect to nt files.

0 Radiographic anthropomorphic ntom.

dentification. A radiographic pomorphic phantom is a device d for medical purposes to simu- human body for positioning ra- hic equipment.

Classification. Class I. The is exempt from the premarket tion procedures in Subpart E 807. The device is exempt from rent good manufacturing prac- ulations in Part 820, with the on of § 820.180, with respect to requirements concerning , and § 820.198, with respect to int files.

50 Radiographic intensifying en.

lentification. A radiographic in- ing screen is a device that is a idiolucent sheet coated with a scent material that transforms

incident X-ray photons into visible light and intended for medical purposes to expose radiographic film.

(b) *Classification.* Class I.

§ 892.1980 Radiologic table.

(a) *Identification.* A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.

(b) *Classification.* Class II.

Subparts C–E—[Reserved]

Subpart F—Therapeutic Devices

§ 892.5050 Medical charged-particle radiation therapy system.

(a) *Identification.* A medical charged-particle radiation therapy system is a device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5300 Medical neutron radiation therapy system.

(a) *Identification.* A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment support, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5650 Manual radionuclide applicator system.

(a) *Identification.* A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class I.

§ 892.5700 Remote controlled radionuclide applicator system.

(a) *Identification.* A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class II.

§ 892.5710 Radiation therapy beam-shaping block.

(a) *Identification.* A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to modify the shape of a beam from a radiation therapy source.

(b) *Classification.* Class II.

§ 892.5730 Radionuclide brachytherapy source.

(a) *Identification.* A radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.

(b) *Classification.* Class II.

§ 892.5740 Radionuclide teletherapy source.

(a) *Identification.* A radionuclide teletherapy source is a device consisting of a radionuclide enclosed in a sealed container. The device is intended for radiation therapy, with the radiation source located at a distance from the patient's body.

(b) *Classification.* Class I.

010

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 22, 1994

Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
UCLA School of Medicine
Harbor-UCLA Medical Center
1000 Carson Street
Torrance, CA 90509

Dear Dr. Marcus:

Thank you for your letter dated November 4, 1994, to the Chairman relating to a rulemaking entitled "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use." Your letter has been referred to me for response.

The contents of your letter were considered by the staff, including Dr. Myron Pollycove, and the Commission. It was determined that your comments identified two subjects which warranted changes in the language of the final rule. The changes are as follows:

(1) A sentence has been added to specify that for radioactive drugs with a half life of greater than 100 days, the time of assay may be omitted. The Commission did not intend to require time of assay for radioactive drugs with very long half lives.

(2) The requirement to place on the label the statement that "other regulatory approvals may be required" has been deleted. The Commission believes that this concern is adequately covered in 10 CFR 35.7.

You will be interested to know that on November 15, 1994, the Commission approved this final rule by a vote of 3-0.

Your letter will become part of the official record for this rulemaking. Once again I would like to thank you for your continued interest in regulations pertaining to the medical issues.

Sincerely,

Anthony N. Tse, Ph.D.
Project Manager
Regulation Development Branch
Office of Nuclear Regulatory Research

November 30, 1994

AD69-2
011 PDR

The Honorable Philip B. Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In the near future the Nuclear Regulatory Commission (NRC) intends to publish in the Federal Register the enclosed final rule. This final rule will amend the NRC's regulations in 10 CFR Parts 30, 32, and 35 to eliminate certain restrictions regarding the medical use of byproduct material.

Specifically, among other things, this final rule will incorporate into NRC's regulations the concept of authorized nuclear pharmacists to allow properly qualified pharmacists greater discretion to prepare radioactive drugs containing byproduct material. Also, the final rule will allow medical use licensees greater discretion to prepare and use radioactive drugs containing byproduct material, to use byproduct material in research involving human subjects, and to use radiolabeled biologics containing byproduct material. NRC licensees conducting research involving human subjects using byproduct material will be required to obtain informed consent of the human subjects and the prior review and approval of an institutional review board in accordance with the Federal Policy for the Protection of Human Subjects. These requirements apply even if the research is conducted, funded, supported, or regulated by another Federal agency which has implemented the Federal policy or is approved by an amendment of an NRC license.

The Commission believes that this final rule will result in a small cost reduction for medical use licensees without compromising the level of protection of public health and safety against radiological hazards.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Michael Bilirakis
Distribution: [PRM35-9.CL2]
RDB/Rdg/Subj-central- EBeckjord, RVollmer, BMorris, FCostanzi, JTelford, ATse

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Date:	11/21/94	11/21/94	11/21/94	11/21/94	11/21/94	11/21/94

Offc:	D:RES	OCA
Name:	EBeckjord	DRathbun
Date:	11/22/94	11/30/94

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November 30, 1994

The Honorable Joseph I. Lieberman, Chairman
Subcommittee on Clean Air and Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

In the near future the Nuclear Regulatory Commission (NRC) intends to publish in the Federal Register the enclosed final rule. This final rule will amend the NRC's regulations in 10 CFR Parts 30, 32, and 35 to eliminate certain restrictions regarding the medical use of byproduct material.

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Alan K. Simpson

Distribution: [PRM35-9.CL2]
RDB/Rdg/Subj-central- EBeckjord, RVollmer, BMorris, FCostanzi, JTelford, ATse

Offc:RDB:DRA:RES	RDB:DRA:RES	RDB:DRA:RES	DD:DRA:RES	D:DRA:RES	DD:CIRC:RES
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Date:11/21/94	11/21/94	11/21/94	11/4/94	11/4/94	11/22/94

Offc:	D:RES	OCA
Name:	EBeckjord	DRathbun
Date:	11/ /94	11/30/94

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November 30, 1994

The Honorable Richard H. Lehman, Chairman
Subcommittee on Energy and Mineral Resources
Committee on Natural Resources
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In the near future the Nuclear Regulatory Commission (NRC) intends to publish in the Federal Register the enclosed final rule. This final rule will amend the NRC's regulations in 10 CFR Parts 30, 32, and 35 to eliminate certain restrictions regarding the medical use of byproduct material.

Specifically, among other things, this final rule will incorporate into NRC's regulations the concept of authorized nuclear pharmacists to allow properly qualified pharmacists greater discretion to prepare radioactive drugs containing byproduct material. Also, the final rule will allow medical use licensees greater discretion to prepare and use radioactive drugs containing byproduct material, to use byproduct material in research involving human subjects, and to use radiolabeled biologics containing byproduct material. NRC licensees conducting research involving human subjects using byproduct material will be required to obtain informed consent of the human subjects and the prior review and approval of an institutional review board in accordance with the Federal Policy for the Protection of Human Subjects. These requirements apply even if the research is conducted, funded, supported, or regulated by another Federal agency which has implemented the Federal policy or is approved by an amendment of an NRC license.

The Commission believes that this final rule will result in a small cost reduction for medical use licensees without compromising the level of protection of public health and safety against radiological hazards.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Barbara Vucanovich

Distribution: [PRM35-9.CL2]
RDB/Rdg/Subj-central-EBeckjord, RVollmer, BMorris, FCostanzi, JTelford, ATse

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Name:	ATse:jw	JTelford	SBahadur	FCostanzi	BMorris	RVollmer
Date:	11/21/94	11/21/94	11/21/94	11/21/94	11/21/94	11/22/94

Offc:	D:RES	OCA
Name:	EBeckjord	DRathbun
Date:	11/22/94	11/30/94

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
Office of Public Affairs
Washington, D.C. 20555

No. 94-182
Tel. 301/415-8200

FOR IMMEDIATE RELEASE
(Wednesday, November 30, 1994

NRC CHANGES REGULATIONS TO INCREASE FLEXIBILITY IN MEDICAL USES OF NUCLEAR MATERIAL

The Nuclear Regulatory Commission is changing its regulations for the medical use of nuclear material to provide greater flexibility for authorized physicians and qualified pharmacists.

The changes are responsive to a petition for rulemaking submitted to the NRC by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The revisions will:

(1) Include the concept of an "authorized nuclear pharmacist," so that pharmacists who meet specified training and experience requirements would be authorized to prepare radioactive drugs from scratch. Currently, these pharmacists are restricted to preparing radioactive drugs using special kits and certain devices, known as "generators," that produce needed short-lived radioactive materials from other--more stable and long-lived--radioactive materials.

(2) Allow the use of radioactive materials in research involving human beings, provided that the licensee obtains informed consent and approval of the research project by an institutional review board, as described in the Federal Policy for the Protection of Human Subjects. Currently NRC licensees must get special permission to use radioactive materials in research involving human beings. The proposed rule would allow the practice on a more routine basis.

(3) Allow the use of radiolabeled biologics (such as antibodies to which radioactive material has been affixed). The biologics could be used for purposes such as to (a) detect the presence of tumors that may not be detected by other means and (b) treat the tumors by directing highly radioactive antibodies to these sites. Current NRC regulations do not specifically permit licensees to use radiolabeled biologics, although research uses have been permitted by special permission for certain licensees.

(4) Continue the flexibility provided in an NRC interim rule published on August 23, 1990. The interim rule allowed physicians more discretion in using radioactive drugs, since it deleted the requirement in the previous regulations that physicians must follow (a) Food and Drug Administration approved package insert instructions regarding indications and method of administration of radioactive drugs to treat patients and (b) manufacturers' instructions for preparing radioactive drugs from kits and "generators." FDA generally does not require physicians to follow these instructions.

The changes also include miscellaneous revisions to clarify, update and simplify the current regulations, such as accepting certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

The Commission does not believe that these changes will result in any significant increase in radiation exposure to the public or the environment beyond the exposures currently resulting from medical uses of nuclear material.

A proposed rule on this subject was published in the Federal Register for public comment on June 17, 1993. Minor changes made as a result of the comments received are discussed in a Federal Register notice issued on November 30. The amendments will be effective on January 1.

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Rules and Regulations

Federal Register
Vol. 59, No. 231
Friday, December 2, 1994

AD 69-2
PDR

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 32, and 35

RIN 3150-AD69

Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations for the medical use of byproduct material. This action is being taken in response to a petition for rulemaking. This final rule is intended to provide greater flexibility by allowing properly qualified nuclear pharmacists and authorized users who are physicians greater discretion to prepare radioactive drugs containing byproduct material for medical use. This final rule, while allowing research involving human subjects using byproduct material, requires NRC licensees who conduct such research to obtain the informed consent of the human subjects and the prior review and approval of an "institutional review board" within the meaning of the Federal Policy for the Protection of Human Subjects. This final rule also allows medical use of radiolabeled biologics. In addition, this final rule contains other miscellaneous and conforming amendments necessary to clarify or update the current regulations.

EFFECTIVE DATE: January 1, 1995.

ADDRESSES: Copies of the public record, including the final regulatory analysis and any public comments received on the proposed rule, may be examined and copied for a fee in the Commission's Public Document Room at 2120 L Street, NW. (Lower Level), Washington DC.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6233.

SUPPLEMENTARY INFORMATION:

I. Background

The Petition for Rulemaking

In early 1989, the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) approached the NRC staff with concerns that the Commission's regulations failed to accommodate the functions and responsibilities of the practice of nuclear pharmacy. At the suggestion of the NRC staff, the ACNP and SNM submitted a petition for rulemaking requesting the Commission to amend its regulations to fully recognize the role of licensed nuclear pharmacists and physicians. On September 15, 1989 (54 FR 38239), the Commission published in the **Federal Register** a notice of receipt of a petition for rulemaking for public comment (PRM-35-9).

During the development of the ACNP-SNM petition, one NRC staff member provided substantial assistance in the preparation of the petition. However, that individual has not participated in the NRC's resolution of the petition or in the development of this rule. Another NRC staff member reviewed the petition prior to its formal submittal to the Commission and participated, to some extent, in the NRC's resolution of the petition and in the development of the rule. The Commission, while aware of this background, considered the petition on its own merits.

The petition included the following requests:

A. The petitioners requested that authorized users who are physicians (physician authorized users) be given greater flexibility regarding the medical use of radiopharmaceuticals containing byproduct material. Specifically, the petitioners requested that these physicians be permitted to: (1) Use radiopharmaceuticals to treat diseases that are not listed in the U.S. Food and Drug Administration (FDA) approved package insert; (2) Use methods of administration of radiopharmaceuticals that are not listed in the package insert; (3) Use radiopharmaceuticals other than those for which the FDA has accepted an Investigational New Drug (IND) or an approved New Drug Application (NDA); (4) Prepare radiopharmaceuticals using radionuclide generators and reagent kits in a manner other than in accordance with the manufacturer's instructions; and (5) Compound radiopharmaceuticals in accordance with State law.

B. The petitioners requested that the NRC recognize the practice of nuclear pharmacy and the certification of nuclear pharmacists by the Board of Pharmaceutical Specialties. Specifically, the petitioners requested that nuclear pharmacists be permitted to: (1) Compound radiopharmaceuticals as allowed by State or FDA regulations; (2) Compound radiopharmaceuticals whose manufacture and distribution are not regulated by the State or FDA; (3) Prepare radiopharmaceuticals using radionuclide generators and reagent kits in a manner other than in accordance with the manufacturer's instructions; (4) Produce reagent kits; and (5) Dispense radiopharmaceuticals that are not regulated by the FDA.

C. Additionally, the petitioners requested that the NRC: (1) Permit categories of research using radioactive drugs that do not require an IND, such as research approved by a Radioactive Drug Research Committee (RDRC); (2) Permit the use of radiolabeled biologics for which the FDA has issued a license in response to a product license application (PLA); and (3) Clarify its regulations pertaining to specific licenses of broad scope.

Earlier NRC Efforts

In response to the **Federal Register** notice that announced the receipt of the petition, 466 comment letters were received. About 99 percent of the commenters supported and agreed with the petition. After consideration of the public comment letters and consultation with the FDA staff, the Commission determined that some issues should be addressed promptly.

On August 23, 1990 (55 FR 34513), the Commission published an Interim Final Rule to allow, for a period of 3 years, the use of therapeutic radiopharmaceuticals for indications not listed in the package insert and to allow departures from the manufacturer's instructions for preparing diagnostic radiopharmaceuticals using radionuclide generators and reagent kits. On July 22, 1993, the Commission extended the expiration date of the

Interim Final Rule from August 23, 1993, to December 31, 1994. The action allows licensees to continue to use byproduct material under the provisions of the Interim Final Rule until the Commission completes this final rule.

In a parallel effort, the NRC continued to work on the remaining issues in the ACNP–SNM petition. On August 7, 1991, the NRC conducted a public workshop in Rosemont, Illinois, to present "strawman" language on the training and experience criteria for authorized nuclear pharmacists to representatives of the following organizations: Board of Pharmaceutical Specialties, American Board of Science in Nuclear Medicine, National Association of Boards of Pharmacy, Committee on Radionuclides and Radiopharmaceuticals of the U.S. Council for Energy Awareness, American Pharmaceutical Association, American Society of Hospital Pharmacists, and three graduate schools of pharmacy. Subsequently, the NRC also discussed the proposed resolution of these issues in meetings with the FDA, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), and the Agreement States. This rulemaking is the evolutionary result of numerous meetings with the aforementioned groups.

NRC's Policy

In a policy statement published on February 9, 1979 (44 FR 8242), entitled "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," the NRC stated:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

In conformance with this policy, the Commission is eliminating certain restrictions in the NRC regulations on the practices of medicine and pharmacy (e.g., compounding), and is providing the authority for research involving human subjects and the use of radiolabeled biologics. The Commission believes that these restrictions can be eliminated without compromising the level of protection of public health and safety against radiological hazards. The Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients or human research subjects and recognizes that nuclear pharmacists have the primary responsibility for the preparation of radioactive drugs. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians and pharmacists will make decisions that are in the best interest of their patients or human research subjects. Furthermore, the pharmacological aspects of radioactive drugs, including drug safety and efficacy, are regulated by the FDA or the States.

II. The Proposed Rule, Public Comments, and NRC Responses

The Commission published the proposed rule in the **Federal Register** on June 17, 1993 (58 FR 33396), and provided a 120-day public comment period. About 2,500 copies of the notice of the proposed rulemaking were mailed to all applicable NRC licensees, Agreement State and Non-Agreement State agencies, and other interested groups.

The NRC received 284 comment letters in response to the proposed rule. There were 280 letters in support of the proposed rule, 1 letter in opposition to the proposed rule, and 3 letters provided comments without specifically indicating support for or opposition to the proposed rule. There were 182 letters from individuals working in commercial pharmacies, 3 from pharmaceutical manufacturers, 6 from hospitals, 7 from professional associations, 6 from universities, 5 from governmental agencies, and 75 who did not indicate their affiliations. In terms of commenters' professions or qualifications, the vast majority of letters were from pharmacists.

Public comments and the NRC's responses are presented below. General comments are presented first, followed by specific comments associated with individual sections of the rule for which comments were received. The discussion of the changes in the proposed rule language is presented in section III entitled "Discussion of Final Rule Text." Referring to section V, entitled "Text of Final Regulations," may expedite the reader's understanding of the public comments and the NRC's responses.

General Comments

(1) *Comment.* The NRC is "straying very far" from its mandate and competence in regulating the medical uses of byproduct material. The commenter appended a copy of section 104 of the Atomic Energy Act, entitled "Medical Therapy and Research and Development," as rationale for the commenter's viewpoint.

Response. The Commission's statutory mandate in the Atomic Energy Act of 1954, as amended, includes all uses of byproduct, source, and special nuclear material. Specifically, section 81 of the Act *prohibits*, without Commission authorization, the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, or export of byproduct material (42 U.S.C. 2111). Also, section 161 of the Act states (in part):

> The Commission is authorized to establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and *byproduct material* as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property (emphasis added).

Therefore, the Commission has broad statutory responsibility to regulate all uses of byproduct material, including medical use.

Section 104(a) of the Atomic Energy Act states:

> The Commission is authorized to issue licenses to persons applying therefor *for utilization facilities for use in medical therapy*. In issuing such licenses the Commission is directed to permit the widest amount of effective medical therapy possible with the amount of *special nuclear material* available for such purpose and to impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public (42 U.S.C. 2134(a)) (emphasis added).

Section 104(a) on its face applies only to medical therapy licensees for using "utilization facilities" (i.e., nuclear reactors) and "special nuclear material." No "minimum regulation" directive governs the Commission's regulation of byproduct material. This section does not even apply to the medical use of byproduct material, which falls within the NRC's broad standard-setting authority in sections 81 and 161 of the Act. Even if the commenter were correct that the NRC had a statutory obligation to minimize regulation, this rule eliminates certain restrictions in the regulation of the medical use of byproduct material, furthering that purpose. The Commission is, in fact, imposing the minimum amount of regulation commensurate with the need for protection of the public health and safety.

Regarding the NRC's competence, "[t]he substantive area in which an agency is deemed to be expert is

determined by statute." *Massachusetts v. United States*, 856 F.2d 378, 382 (1st Cir. 1988). *See also Commonwealth of Massachusetts v. NRC*, 924 F.2d 311, 324 (D.C. Cir.), *cert. denied*, 112 S.Ct. 275 (1991). The Atomic Energy Act commits to the NRC the duty of regulating the use of byproduct materials, including radioactive drugs, to protect public health and safety and as a matter of law the NRC is deemed "expert" in making technical and policy judgements in this field.

The NRC has long experience in regulating nuclear medicine and "[i]n recent years has increased its recruitment of personnel who have experience and knowledge either in nuclear medicine or in radiation therapy" (56 FR 34104; July 25, 1991). Since the Commission's inception, it has been accountable for the regulation of medical uses of byproduct material. It has licensed, inspected, collected and analyzed data in this field for many years, and has issued and administered various forms of regulations.

Furthermore, this rulemaking is not about what dosage of a radioactive drug should be prescribed to treat or diagnose a patient. It is about the qualifications of individuals performing NRC-licensed activities (e.g., authorized nuclear pharmacists) that are necessary to protect the health and safety of patients and workers from radiological hazards. This rule, in other words, does not intrude on medical judgment. Moreover, the NRC has highly qualified staff and extensive experience in determining radiation safety qualifications.

In addition, the NRC has an advisory committee (the Advisory Committee on the Medical Uses of Isotopes or "ACMUI"), which, since its establishment many years ago, has advised the NRC on rulemakings and other initiatives related to the medical uses of byproduct material. The membership of the ACMUI includes a broad spectrum of expertise, such as physicians (i.e., in nuclear medicine, cardiology, and radiation oncology), medical physicists, pharmacists, medical researchers, practicing technologists, hospital administrators, state medical regulators, Food and Drug Administration representatives, and a patient rights representative. The NRC also has a visiting medical fellows program that allows selected physicians or pharmacists to work for NRC for a period of 1 to 2 years. Both ACMUI and the visiting medical fellows provided advice to the NRC during the development of this rule.

(2) *Comment.* The NRC is attempting to duplicate regulation by other federal, state, and national entities which already have appropriate responsibility in the areas of medicine and pharmacy.

Response. This final rule is not duplicating regulation by other federal or state agencies. In fact, this rule is designed to avoid duplication of the regulations of other federal agencies (e.g., see response to comments on § 35.6). In the area of medical use of byproduct material, the NRC and FDA signed a Memorandum of Understanding (58 FR 47300; September 8, 1993) to coordinate existing NRC and FDA regulatory programs. Generally speaking, FDA regulates the manufacture and distribution of radioactive drugs and medical devices for safety and efficacy, while the NRC regulates radiation safety associated with the actual use of these products.

(3) *Comment.* The preamble to the proposed rule gives the impression that the NRC would allow nuclear physicians and nuclear pharmacists to use unregulated, dangerous radioactive drugs. In addition, a commenter stated that, under State Pharmacy law, a licensed pharmacist may delegate certain duties to non-pharmacist individuals if the pharmacist provides "direct supervision." Is it the NRC's intent to permit the authorized nuclear pharmacist to delegate the full range of professional duties to non-pharmacist individuals?

Response. The preamble to the proposed rule stated that a licensee must meet the Commission's regulations regarding radiation safety of the workers and the public, including patients, and that the licensee is not relieved from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs. Because the FDA and States regulate the safety and efficacy of radioactive drugs, the licensee must also follow their regulations when using radioactive drugs. The Commission will allow an authorized nuclear pharmacist to delegate a full range of duties to a non-pharmacist individual provided that the individual is properly supervised (i.e., according to § 35.25).

(4) *Comment.* The final rule should be effective immediately upon publication in the Federal Register instead of being effective 6 months after publication.

Response. The Commission agrees that licensees may not need 6 months to implement this final rule. However, with limited exceptions, section 553(d) of the Administrative Procedure Act (APA) provides that "[t]he required publication or service of a substantive rule shall be made not less than 30 days before its effective date." The commenter has not persuaded the NRC that good cause exists for making immediately effective this final rule, which in part, imposes new substantive requirements. Therefore, the effective date will be 30 days after publication of this rule in the Federal Register.

(5) *Comment.* The NRC should provide a mechanism for "grandfathering" qualified nuclear pharmacists who are currently working in hospital-based nuclear pharmacies, similar to the mechanism proposed for "grandfathering" qualified individuals working in commercial nuclear pharmacies.

Response. The Commission agrees with this comment because a qualified nuclear pharmacist should be "grandfathered" regardless of whether the individual is currently working in a commercial nuclear pharmacy or a hospital-based nuclear pharmacy. Therefore, § 35.981 entitled "Training for experienced nuclear pharmacists," has been added to this final rule. This section is similar to § 32.72 in the proposed rule for "grandfathering" qualified individuals working in commercial nuclear pharmacies. The Commission believes that this limited "grandfathering" is justified provided: (1) This individual is currently working in a nuclear pharmacy; (2) this individual has completed a structured educational program as specified in § 35.980(b)(1); and (3) the qualifications of this individual would be reviewed and approved by NRC before a licensee may allow this individual to work as an authorized nuclear pharmacist.

(6) *Comment.* Several commenters requested that the following items be addressed in this rulemaking: (a) Handling of brachytherapy radioactive sources for temporary implants related to I–125 eye plaques, wherein the patient goes home and returns several days later for removal of the sources; (b) Changing the person who signs the records of sealed source leak tests, sealed source inventories, and surveys of sealed source storage areas from the Radiation Safety Officer to the individual who performs these tasks; and (c) Permitting licensees to allow Radiation Safety Officers who meet certain requirements to work without first obtaining a license amendment (similar to the provisions proposed for authorized users and authorized nuclear pharmacists).

Response. These items will not be addressed because they are beyond the scope of this rulemaking.

Specific Comments

Section 32.72 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use Under 10 CFR Part 35

Several commenters addressed the use of the term "radioactive drug." These comments and the NRC's responses are summarized below.

(1) *Comment.* One commenter stated that "the FDA has a specific definition which it uses for radiopharmaceuticals, and I am not aware that it will similarly replace this word with that of radioactive drug." Also, the commenter questioned whether the term "radioactive drug" included radiolabeled biologics.

Response. FDA regulations define the term "radioactive drug" (21 CFR 310.3) but do not define the term "radiopharmaceutical." As stated in the preamble to the proposed rule, the term "radioactive drug" includes a radiolabeled biologic, which is an accurate usage for both NRC and FDA regulations.

(2) *Comment.* The medical use of byproduct material may be approved by the FDA as a radioactive drug or a device. If it is approved as a device, not a radioactive drug, would the proposed changes create regulatory barriers in such situations?

Response. This rule does not impose any new regulatory requirements for the use of devices containing byproduct material. Therefore, this rule would not create regulatory barriers for the use of such devices.

Section 32.72(a)(2)

Several commenters requested clarification concerning the proposed requirement that a nuclear pharmacy or a drug manufacturer must obtain a Part 32 license. These comments and the NRC's responses are summarized below.

(1) *Comment.* The NRC should continue to permit Part 33 or 35 medical use licensees to share a nuclear pharmacy without requiring a Part 32 license.

Response. The Commission currently permits the nuclear pharmacy of a Part 33 or 35 medical use licensee to distribute radioactive drugs to a limited set of medical use licensees through a license amendment approval on a case-by-case basis. This is the context in which such licensees may "share" a nuclear pharmacy. The Commission believes that Part 33 or 35 licensees who have been granted this authority could continue to operate a nuclear pharmacy provided that the nuclear pharmacy:

(i) Complies with the safety requirements specified in 10 CFR 32.72(a)(3), (a)(4), and (c);

(ii) Is operated by a medical use licensee; and

(iii) Only engages in limited distribution to a specified set of medical use licensees but does not engage in commercial distribution.

Other Part 33 or 35 medical use licensees seeking this authority must first apply for a license amendment and receive an authorization for limited distribution pursuant to Part 32. The fees specified in Category 3C of 10 CFR 170.31 and 10 CFR 171.16 are assessed for this type of authorization. As provided in footnote 1(d)(2) of 10 CFR 170.31, there is an application fee (fee Category 3C) to add this type of authorization. Upon issuance of the license amendment adding this authorization, the licensee will be subject to the licensing and inspection fees in fee Category 3C of 10 CFR 170.31 and the annual fees in fee Category 3C of 10 CFR 171.16. These fees are in addition to any other fee categories covered by the existing license.

However, in those cases where a small number of Part 35 licensees wish to transfer unsealed byproduct material among themselves, the NRC will consider granting an exemption pursuant to 10 CFR 35.19. 10 CFR 170.31 (footnote 2) specifies the fees for such exemption requests. For existing Part 35 licensees, requests for an exemption under 10 CFR 35.19 are subject to the amendment fees specified in 10 CFR 170.31, or fee Category 7B or 7C, as applicable.

(2) *Comment.* The NRC should continue to permit Part 33 licensees who are authorized to produce radioactive drugs to be used only for research experiments to distribute these drugs to medical use licensees.

Response. The Commission currently permits such a Part 33 licensee to distribute, on a limited basis, radioactive drugs to be used only for research experiments through a license amendment approval on a case-by-case basis. The Commission believes that Part 33 licensees who have been granted this authority could continue to distribute these drugs provided that the Part 33 licensee complies with safety requirements specified in 10 CFR 32.72(a)(3), (a)(4), and (c). Other Part 33 licensees seeking this authority must apply for a license amendment and receive an authorization for limited distribution pursuant to Part 32. This type of authorization is subject to the fees specified in fee Category 3C of 10 CFR 170.31 and 171.16. As provided in footnote 1(d)(2) of 10 CFR 170.31, there is an application fee (fee Category 3C) to add this type of authorization. Upon issuance of the license amendment adding this authorization, the licensee will be assessed the licensing and inspection fees in fee Category 3C of 10 CFR 170.31 and the annual fees in fee Category 3C of 10 CFR 171.16. These fees are in addition to any other fee categories covered by the existing license.

Section 32.72(a)(4).

There were numerous comments addressing the labeling requirements. These comments and NRC's responses are summarized below.

(1) *Comment.* Several commenters stated that the NRC has no legal jurisdiction over drug labeling and should not require drug labeling because it is regulated by the FDA. Another commenter supported the proposed labeling requirements and stated that its facility has already included all information specified in the proposed rule.

Response. The Commission has broad authority under sections 81 and 161 of the Atomic Energy Act, as amended, including authority to establish by rule, regulation, or order, such standards and instructions to govern the possession and use of byproduct material. Therefore, the Commission has jurisdiction to require labeling of radioactive drugs containing byproduct material and is currently requiring that specific information be included on labels.

The Commission's labeling requirements are not intended to duplicate FDA requirements, but are intended to provide information related to radiation safety. These labels are needed for:

(i) Hospital workers to ensure that the radioactive drug is the correct drug and the correct dosage; and

(ii) Transport workers to identify the contents of a vial, container, or package, and to take appropriate actions in the event of any transportation accident.

(2) *Comment.* It would be very costly to have inspectors check 12 million drug labels. The commenter believes that this activity would be entirely cost-ineffective.

Response. The modifications to current § 32.72(a)(4) are intended to clarify the existing labeling requirements, except for the addition of "time of assay." Thus, the Commission believes that licensees will not incur significant additional cost associated with these modifications. In terms of inspections, the NRC inspectors do not check the label of every container or package of a radioactive drug. They may

conduct spot checks. Thus, there will not be a significant cost for NRC inspectors either.

(3) *Comment.* The syringe label should not be limited to the clinical procedure. On the other hand, it is unnecessary to require that the label, or the leaflet or brochure that accompanies the radioactive drug, contain all of the statements specified in the proposed rule.

Response. The regulatory text in this section states: "In addition, the label for the syringe or syringe radiation shield must also contain the clinical procedure to be performed or the patient's or the human research subject's name." Thus, the clinical procedure is an additional item but not the only item on the label.

Regarding the statements that must be included in the leaflet or brochure, the Commission believes these statements are necessary because they serve as warnings to individuals who are not authorized to use the byproduct material. However, the statement that "other regulatory approvals may be required" has been deleted because this concern is already covered by 10 CFR 35.7.

(4) *Comment.* It is unclear as to the legal origin of the statement that "NRC's labeling requirements are independent of requirements of the U.S. Food and Drug Administration (FDA)."

Response. This comment quotes the last sentence of § 32.72(a)(4) of the proposed rule, stating that: "NRC's labeling requirements are independent of requirements of the U.S. Food and Drug Administration (FDA)." This comment appears to question the NRC's statutory authority for the quoted statement. As previously stated in response to comment 1 on § 32.72(a)(4), the NRC's statutory authority to impose requirements with respect to the labeling of radioactive drugs containing byproduct material derives from its authority under the Atomic Energy Act (primarily sections 81 and 161b) to regulate byproduct material. The quoted sentence makes it clear that NRC's labeling requirements are separate from the labeling requirements of FDA.

Section 32.72(b)

There were several comments concerning this paragraph. These comments and the NRC's responses are discussed below.

(1) *Comment.* The phrase "within 30 days of the date" used in the proposed § 32.72(b)(3) is confusing and should be replaced with "no later than 30 days after the date."

Response. The Commission agrees with the comment. The final rule text has been modified accordingly.

(2) *Comment.* In the preamble of the proposed rule discussing proposed § 32.72(b)(3), the use of the phrase "individual's character" in determining whether the individual should be approved as an authorized nuclear pharmacist appears inappropriate.

Response. The NRC disagrees with this comment. Under sections 182 and 183 of the Atomic Energy Act, the Commission has broad authority over the scope of license applications and the terms of licenses. Section 182(a) includes the authority to require, by rule or regulation, such information as the Commission determines necessary to decide, among other things, the technical *and other* qualifications of the applicant as the Commission may deem appropriate, as well as the applicant's character. Therefore, in determining whether to grant a license or license amendment, or approve an individual to perform licensed activities, the NRC can consider the past performance and character (which may include activities involving improper or illegal practices) of the license applicant, the licensee, or the individual who is to perform licensed activities. An individual occupying the position of a physician authorized user or authorized nuclear pharmacist has the potential to affect the public health and safety. Accordingly, it would be appropriate for the NRC to consider information relating to that individual's "character."

(3) *Comment.* If an authorized nuclear pharmacist decides not to seek recertification as a Board Certified Nuclear Pharmacist, would the individual lose the authorized nuclear pharmacist status?

Response. No. If an individual gained authorized nuclear pharmacist status based on board certification and decided not to seek recertification, this individual may continue to work as an authorized nuclear pharmacist provided this individual continues to be identified as an authorized nuclear pharmacist on a Commission or Agreement State license or on a permit issued by a Commission or Agreement State licensee of broad scope.

(4) *Comment.* Would the scope of "grandfathering" extend beyond the initial transition period?

Response. The Commission believes it is not necessary to limit the "grandfathering" provision to a definite period after the effective date of this final rule. Therefore, there is no time limit for the "grandfathering" provision.

Section 32.72(c)

There were several comments concerning instrumentation. These comments and the NRC's responses are discussed below.

(1) *Comment.* The proposed requirements for linearity and geometry tests are not consistent with methods of assaying alpha or beta emitters, such as liquid scintillation counting.

Response. The regulatory text includes the phrase "as appropriate for the use of the instrument." Therefore, if linearity or geometry tests are not appropriate for an instrument, the tests are not required.

(2) *Comment.* The regulation does not require medical use licensees to measure the activity of a unit dosage of an alpha- or a beta-emitting radionuclide. This provision should also apply to commercial nuclear pharmacies.

Response. Section 35.52(a) will exempt a medical use licensee from measuring the alpha- or beta-activity of a unit dosage, if the licensee obtains that unit dosage from a commercial nuclear pharmacy. This exemption is acceptable because § 32.72(c) will require the commercial nuclear pharmacy to measure that activity before dispensing the radioactive drug. Commercial nuclear pharmacies would be required to measure the alpha- or beta-activity of a unit dosage because, otherwise, it might not be measured by anyone. Therefore, this provision cannot be applied to commercial nuclear pharmacies.

Authorized Nuclear Pharmacist

There were several comments concerning this definition. These comments and the NRC's responses are summarized below.

(1) *Comment.* This definition uses the phrase "a permit issued by a Commission or Agreement State specific licensee of broad scope." Is there a standard format for this permit?

Response. The Commission does not require licensees of broad scope to use a standard format for a permit. The format for this permit may vary from one licensee to another.

(2) *Comment.* The word "or" should be inserted between the first and second paragraphs of this definition.

Response. It is an acceptable regulatory drafting convention that for a sentence with multiple independent conditions, only one "or" is necessary between the last condition and the previous condition to indicate that satisfying any one of the conditions is acceptable. Because this definition has three independent conditions, an "or" between the first and the second condition is not necessary.

Authorized User

Comment. There were several comments concerning the use of the phrase "individual's character" in the preamble of the proposed rule. The commenters stated that the use of the phrase "individual's character" appears inappropriate in considering whether the individual should be approved as an authorized user.

Response. For the same reasons as set forth in response to comment (2) of § 32.72(b), the Commission disagrees with the comment.

Medical Use

There were several comments concerning the addition of human research subjects in the definition of medical use. These comments and the NRC's responses are summarized below.

(1) *Comment.* By including human research subjects under "medical care," it is implied that a physician may be allowed to deliver any radiation dose to a human research subject if the physician can convince the local IRB that the dose is warranted. Also, the concept of implying that human research subjects can be considered as patients may cause difficulty because there are separate laws and considerations for each group.

Response. The definition under discussion is "medical use," not "medical care." The term "medical use" is specifically defined for the purpose of identifying a class of uses involving byproduct material that is regulated by the Commission. By using the term "patients or human research subjects" in connection with a requirement, the Commission states that the requirement applies to both patients and human research subjects. The Commission does not intend to imply that a human research subject can be considered as a patient, nor does the Commission intend to imply that a physician may deliver any radiation dose to a human research subject, without appropriate approval.

The Commission recognizes that there are separate medical or pharmacy laws and considerations governing human research subjects and patients. However, the Commission has determined that the radiation safety requirements in its regulations that are designed to protect patients from radiological hazards are equally applicable to human research subjects.

(2) *Comment.* There could be some difficulty when applying the quality management program to human research subjects. Also, annual review of human use studies is redundant of FDA regulations.

Response. The quality management program (QMP) applies only to research procedures using quantities of byproduct material specified in § 35.32(a)(1). However, because most research procedures use quantities of byproduct material that are less than those specified in § 35.32, the QMP would not be required for these research procedures.

The review specified in § 35.32(b) applies only to human research procedures for which written directives are required. The review includes evaluation of a representative sample of administrations, recordable events, and misadministrations, to verify compliance with the QMP. These evaluations are specifically related to the requirements in the Commissions's regulations, which are not redundant of FDA regulations.

Section 35.6 Provisions for Research Involving Human Subjects

In the preamble of the proposed rule, the Commission solicited public comment on the number and type of research activities which would not be funded by another Federal agency which has adopted the Federal Policy and which would require a license amendment under the proposed rule. No comments on the number and type of such research activities were received.

Also, the Commission solicited public comment on whether it should broaden or narrow its focus to require compliance with all or none of the provisions of the Federal Policy or equivalent license conditions. The Commission stated that in making these comments, consideration should be given to the fact that all radiation safety provisions of 10 CFR part 35 would be made applicable to research involving human subjects. Several comments were received related to this topic. These comments and the NRC's responses are summarized below.

(1) *Comment.* Omit all regulation of human research with radioactive material because the FDA handles this very nicely.

Response. The Commission cannot omit all such regulation because it has the responsibility for ensuring adequate protection of public health and safety related to the use of byproduct material, including uses involving human research subjects.

In view of the fact that this final rule would specifically permit, in certain circumstances, NRC licensees to use radioactive drugs containing byproduct material for research involving human subjects, the Commission has the responsibility to address the protection of the rights of those human subjects. At a minimum, this final rule requires NRC licensees who conduct such research to obtain the informed consent of the human research subjects and the prior review and approval of an IRB, within the meaning of the Federal Policy for the Protection of Human Subjects. These requirements apply whether or not the research is conducted, funded, supported, or regulated by another federal agency which has implemented this Federal Policy or is approved by the amendment of an NRC license. However, NRC licensees whose human research is covered by the Federal Policy as adopted by another federal agency, may conduct such research without prior NRC approval. In this way, the provisions of this rule are designed to avoid duplication of the regulations of other federal agencies which have adopted the Federal Policy, including the FDA.

(2) *Comment.* The NRC should take steps to ensure that all provisions of the Federal Policy for the Protection of Human Subjects are met.

Response. The basic safety objectives and ethical principles of the Federal Policy will be met by requiring licensees to obtain the informed consent of the human research subjects and prior approval by an IRB. However, some provisions of the Federal Policy are not directly applicable to the Commission's oversight of its licensees, such as the "Use of Federal Funds," "Evaluations of Proposals for Research to be Conducted or Supported by a Federal Department or Agency," and "Early Termination of Research Support." Therefore, NRC does not need to take steps to ensure that all provisions are met.

On the other hand, the proposed rule did not explicitly state that the required informed consent and IRB approval must be in accordance with the provisions of the Federal Policy for the Protection of Human Subjects. Therefore, a phrase "in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects" has been added to the text of the final rule to clarify this point.

There were comments concerning the addition of "human research subjects" in the definition of "medical use" and the broadening of the quality management program to include human research subjects. These comments and NRC's responses are summarized in the discussion of the definition of "medical use" under § 35.2.

Section 35.14 Notification

Comment. Several commenters stated that the phrase "within 30 days of the

date" in the proposed § 32.72(b)(3) may be misinterpreted and suggested that a new phrase "no later than 30 days after the date" should be used.

Response. See response to comment (1) of section 32.72(b).

Section 35.22 Radiation Safety Committee

Comment. There were two comments concerning this section. One commenter agreed with the proposed change. The other commenter stated that the proposed change was not warranted because the Radiation Safety Committees (RSC) are overburdened by other duties.

Response. The Commission believes that it is important for the RSC to review the training and experience of authorized users and authorized nuclear pharmacists and to approve or disapprove any such individuals because this review and the approval or disapproval by RSC is a key factor in the program to ensure radiation safety. Furthermore, existing regulations already require the RSC to perform such review and approval or disapproval of authorized users, Radiation Safety Officers, and teletherapy physicists. By adding authorized nuclear pharmacists to the review and approval or disapproval process of the RSC, the Commission does not believe that a significant burden will be added to the RSC's responsibilities because it is expected that a relatively small number of authorized nuclear pharmacists will be included in Part 35 licenses.

Section 35.25 Supervision

Comment. Several commenters stated that this section should not be so restrictive and that instructions to workers can only be provided by the supervising individuals. These commenters suggested that the provision for instructing workers may be delegated to other qualified individuals. Similarly, they suggested that periodic review of the work of the supervised individuals may also be delegated to other qualified individuals.

Response. The Commission agrees that the workers may be instructed by the licensee, the supervising individuals, or other qualified individuals as long as the instructors are knowledgeable about the subject areas. The regulatory text has been revised to indicate that although the licensee may delegate these tasks to other qualified individuals, the licensee retains the responsibility for instructing workers.

However, the requirement for periodically reviewing the work of supervised individuals remains with the supervising authorized nuclear pharmacist or physician authorized user. The Commission believes that the supervising individual is in a better position to review the work than another individual.

Section 35.27 Visiting authorized user.

Comment. One commenter suggested that this section should be retained. The commenter stated that the paperwork associated with the proposed notification (§ 35.14) would be unduly burdensome for temporary authorized users who provide coverage during another authorized user's vacation or sickness.

Response. The Commission disagrees with the commenter. When allowing a temporary authorized user to work, the licensee does not need to notify the NRC each time that the individual provides coverage during another authorized user's vacation or sickness. Under the notification requirement (§ 35.14), the licensee needs to notify the NRC no later than 30 days after the date the licensee permits the individual to work as a temporary authorized user. The next notification is when that individual permanently discontinues as a temporary authorized user. A notification is not required during each period of coverage between the beginning and the termination of the service of the temporary authorized user. This notification procedure also applies to a temporary authorized nuclear pharmacist. Thus, this section has been removed.

Section 35.50 Possession, Use, Calibration, and Checks of Dose Calibrators.

Several comments were received related to this section. These comments and NRC's responses are summarized below.

(1) *Comment.* The proposed phrase "over the range of its use between the highest dosage that will be administered to a patient or human research subject and 1.1 megabecquerels (30 microcuries)" should be clarified. "Over the range of its use" could mean between the highest and lowest dosages that will be administered; the lowest dosage may not be 1.1 megabecquerels.

Response. The Commission agrees with the comment. The final amendment will be modified to delete the phrase "over the range of its use."

(2) *Comment.* Linearity tests for a dose calibrator should cover the range from the highest patient dosage to the lowest patient dosage that will be administered by a licensee. The lowest dosage could be in microcurie quantities for many licensees. Thus, it is not necessary to test linearity to 1.1 megabecquerels (30 microcuries).

Response. The intent of changing the lower limit of the linearity tests from 10 microcuries to 30 microcuries is to conform with the requirements of the Quality Management Program (§ 35.32) and to relieve a minor burden for measuring activities between 10 and 30 microcuries without reducing radiation safety. To go beyond this by changing this limit to the lowest patient dosage would have ramifications on the constancy checks, accuracy tests, and recordkeeping requirements (i.e., §§ 35.50(b)(1), (b)(2), and (b)(3); and 35.53(a), (b), and (c)(3)). Therefore, deleting this specific lower limit is beyond the scope of this rulemaking.

(3) *Comment.* In expressing the units in both English units and SI units, English units should be first, followed by SI units in parentheses. Also, is there any scientific rationale for the precision implied by 1.1 mBq, instead of using 1 mBq?

Response. The Commission published a policy statement entitled "Conversion to the Metric System" (57 FR 46202; October 7, 1992). This policy statement specifies that the first unit will be in the SI unit with the English unit shown in brackets. In terms of significant digits, the implied uncertainty for 30 microcuries is somewhere between 29 and 31 microcuries and for 1.1 mBq is somewhere between 1.0 and 1.2 mBq. If 1 mBq is used, the implied precision would be less. Therefore, 1.1 mBq has been retained in the final rule.

Section 35.52 Possession, Use, Calibration, and Checks of instrumentation to measure dosages of alpha- or beta-emitting radionuclides.

There were several comments concerning this section. These comments and the NRC's responses are discussed below.

(1) *Comment.* The proposed requirements for linearity and geometry tests are not consistent with methods of assaying alpha or beta emitters, such as liquid scintillation counting.

Response. The regulatory text includes the phrase "as appropriate for the use of the instrument." Therefore, if linearity or geometry tests are not appropriate for an instrument, the tests are not required.

(2) *Comment.* Does the term "unit dosage" include a vial that contains multiple dosages?

Response. A unit dosage can be either a pre-filled syringe or a vial that contains a prescribed dosage for a patient or a human research subject. Thus, a vial containing multiple dosages is not a unit dosage.

(3) *Comment.* In some cases, it may not be practical to order an exact unit dosage before the administration to a patient or human research subject. For example, the size of a brain cyst is determined during surgery and a precise dosage cannot be prescribed before the operation.

Response. In this example, an estimated unit dosage must first be ordered from the nuclear pharmacy. After the physician authorized user determines the precise dosage needed for the individual, the licensee may use either volume or weight to draw the precise dosage from the vial. The use of volume or weight for drawing a smaller dosage from a vial containing an estimated dosage is acceptable because that vial contains only the estimated dosage for one individual. Thus, even if an error is made, the maximum error would be limited to the estimated dosage.

(4) *Comment.* When drawing a dosage from a vial containing multiple dosages, a licensee should be allowed to determine the dosage by using volume and a measurement relative to some standard.

Response. Relative measurement of the alpha- or beta-activity of a radioactive drug could be inaccurate for a variety of reasons, including inconsistent placement of the vial in the instrument's chamber. Without specific details of the procedure for this relative measurement, the accuracy of the measurement is unknown. Therefore, the proposed method of using volume and a measurement relative to some standard cannot be generically accepted. However, if a medical use licensee would like to propose a specific set of procedures for a relative measurement of a particular isotope that would provide acceptable accuracy, the licensee may apply for a license amendment on a case-by-case basis.

Section 35.53 Measurement of Dosages of Unsealed Byproduct Material for Medical Use

There were some comments concerning measurements of dosages. These comments and NRC's responses have been discussed under § 35.52.

Section 35.100 Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion

There were several comments concerning this section. These comments and the NRC's responses are discussed below.

(1) *Comment.* The NRC should continue to permit medical use licensees to share a nuclear pharmacy without requiring a Part 32 license.

Response. See response to comment ¶ (1) of section 32.72(a)(2).

(2) *Comment.* Section 35.100 should be modified to allow a medical use licensee to obtain a radioactive drug only for research purposes from those Part 33 licensees who are authorized to manufacture and distribute radioactive drugs to be used only for research experiments.

Response. The Commission currently permits a Part 33 licensee to distribute, on a limited basis, radioactive drugs to be used only for research experiments through license amendment approvals on a case-by-case basis. As discussed in the response to comments on 10 CFR 32.72(a)(2), Part 33 licensees seeking this authority must first obtain a license amendment and receive an authorization for limited distribution pursuant to Part 32. Therefore, it is not necessary to modify § 35.100 because it will allow medical use licensees to receive radioactive drugs from a Part 33 licensee authorized for limited distribution.

Section 35.910 Training for Uptake, Dilution, and Excretion Studies

Comment. One commenter stated that the proposed amendment to this section would impose severe restrictions on basic human research. The commenter further stated that researchers who desire approval to administer radioisotopes for one or two basic studies in humans and who are not preparing to become nuclear medicine physicians, will not meet these strict criteria.

Response. Under the NRC's existing regulatory framework, administering byproduct material to a patient or a human research subject must be done by a physician authorized user or by an individual under the supervision of a physician authorized user. The use of the term "patient or human research subject" in this section is to clarify that, if a researcher intends to conduct basic studies using human subjects involving byproduct material, it is necessary to have a physician authorized user provide supervision so that the researcher may administer byproduct material to human research subjects. This is an existing regulatory position and it has not been changed by this rulemaking.

Section 35.930 Training for Therapeutic Use of Unsealed Byproduct Material

Comment. One commenter stated that the certification by the American Osteopathic Board of Radiology (AOBR) should be recognized in all applicable sections in 10 CFR Part 35. Under the existing regulations, the Commission has recognized AOBR in §§ 35.910, 35.920, 35.940, 35.950, and 35.960, but not in § 35.300.

Response. Following receipt of this comment, the Commission requested additional information from AOBR concerning training and certification criteria for therapeutic use of unsealed byproduct material. After reviewing supporting documents provided by the AOBR, the Commission has determined that the certification of AOBR is equivalent to the certification of American Board of Radiology (ABR). Therefore, recognition of certification by AOBR has been added in § 35.930 of this final rule for certification granted after 1984 because all candidates certified by AOBR since 1984 will meet the NRC's training requirements.

Section 35.972 Recentness of Training

Comment. There were several comments concerning whether the recentness of training should be 5 years as in the existing regulations, or 7 years as in the proposed rule. Some commenters favored 5 years and stated that the clinical practice changes rapidly, thus, 5 years is more appropriate. Other commenters supported 7 years and stated that 5 years would be burdensome and would not ensure superior training.

Response. The training required in Part 35 concerns radiation safety principles and practices for the protection of public health and safety. These radiation safety principles and practices are not expected to change rapidly with time. Therefore, the Commission is adopting 7 years because this will not reduce the level of radiation protection provided to workers and the public but will reduce the regulatory burden imposed on licensees.

Section 35.980 Training for Authorized Nuclear Pharmacist

There were several comments pertaining to this section. These comments and the NRC's responses are summarized below.

(1) *Comment.* The requirement for a preceptor statement is unnecessary and is irrelevant to the mission of the NRC. Many fully qualified nuclear pharmacists would be excluded from being an authorized nuclear pharmacist by this administrative requirement.

Response. The written certification from a preceptor is a necessary part of the training and experience criteria. Even though an individual has completed the required 700 hours of the structured educational program, it is still uncertain as to whether this

individual is capable of independently operating a nuclear pharmacy. The preceptor's statement is needed to ensure that this individual has achieved the competency to do so.

With respect to a nuclear pharmacist who is currently qualified to be an authorized nuclear pharmacist, a new section (§ 35.981) has been added to address this issue.

(2) *Comment.* It appears that the proposed rule is leaning towards board certification as the only available avenue open to a nuclear pharmacist desiring to be recognized as an authorized nuclear pharmacist in the near future.

Response. There are other available avenues for a qualified individual to be recognized as an authorized nuclear pharmacist. Other avenues include: (i) Meeting the training criteria and obtaining a preceptor statement from an authorized nuclear pharmacist; or (ii) Meeting the "grandfathering" provisions as specified in § 35.981 of this final rule.

(3) *Comment.* Whether an individual is qualified as an authorized nuclear pharmacist should be based on education and training, not just based on BPS certification.

Response. The Commission agrees that qualification as an authorized nuclear pharmacist should be based on training and experience. This final rule provides several ways, including BPS certification, to achieve authorized nuclear pharmacist status, all of which include a minimum level of training and experience. The various ways to achieve this status are provided in §§ 35.980 and 35.981.

(4) *Comment.* It is imperative that training programs be monitored by appropriate independent oversight processes (e.g., American Council on Pharmaceutical Education in the case of pharmacy).

Response. The Commission agrees that it could be useful for a training program to be monitored by an independent oversight group. In addition, the Commission encourages voluntary oversight by an independent group such as a professional association. However, given the oversight roles of the preceptor and the Radiation Safety Committee, the Commission does not see a need to incorporate such a requirement.

(5) *Comment.* If an authorized nuclear pharmacist decides not to seek recertification as a Board Certified Nuclear Pharmacist, would the individual lose the authorized nuclear pharmacist status?

Response. See response to comment (3) of § 32.72(b).

(6) *Comment.* It appears that the NRC desires to make "authorized nuclear pharmacist" status available only to those pharmacists who are engaged in active clinical practice settings. This status should be also available to qualified nuclear pharmacists working in facilities other than clinical practice settings, such as in the research laboratories or academic settings.

Response. An authorized nuclear pharmacist who meets the training requirements as specified in § 35.980 should be competent to independently operate a nuclear pharmacy regardless of the setting. When there is a need for an authorized nuclear pharmacist outside the clinical setting, qualified individuals in research laboratories or academic settings may also be designated as authorized nuclear pharmacists.

(7) *Comment.* Authorized nuclear pharmacist status should be available to those individuals who have practiced radiopharmacy for a long time but who are not licensed pharmacists.

Response. The Commission believes that an individual should not practice pharmacy unless this individual is licensed as a pharmacist by a State. Thus, an authorized nuclear pharmacist must be a licensed pharmacist as required by §§ 35.980 and 35.981. However, an experienced individual (e.g., a nuclear chemist) may continue to work in a nuclear pharmacy under the supervision of an authorized nuclear pharmacist or a physician authorized user.

(8) *Comment.* The Florida State Board of Pharmacy issues nuclear pharmacists a separate license based on a review of the individual's qualification by its Nuclear Pharmacy Committee. Additionally, it requires a mandatory 12-hours per annum of continuing education in a specific range of topic areas pertinent to nuclear pharmacy practice. With this type of licensing review process already in place, how would the NRC consider applying this towards its "limited grandfathering" process for granting "authorized nuclear pharmacist" status to Florida nuclear pharmacists? Would the Commission consider this established Florida process for pharmacists as carrying sufficient weight which might serve as a third alternative to its proposed language in 10 CFR 35.980?

Response. Section 35.980 specifies that a pharmacist could be qualified as an authorized nuclear pharmacist in two ways: (i) Through BPS certification; or (ii) through a structured educational program and a preceptor's statement. Because qualification as an authorized nuclear pharmacist depends primarily on training and experience, if Florida licensed nuclear pharmacists currently meet either (i) or (ii), they could qualify as authorized nuclear pharmacists. If they do not meet either (i) or (ii), they would need either more training or experience, or a preceptor's statement to qualify. Therefore, there is no benefit to adding a third alternative to 10 CFR 35.980.

For "grandfathering" an experienced nuclear pharmacist, a new section (§ 35.981) has been added to the final rule. This section specifies that an experienced pharmacist will be given authorized nuclear pharmacist status if the individual:

(i) Is a licensed pharmacist,

(ii) Is currently working in a nuclear pharmacy, and

(iii) Has completed a structured educational program as specified in § 35.980(b)(1).

A Florida licensed nuclear pharmacist who is currently working in a nuclear pharmacy could satisfy the first two criteria. However, the comment letter did not provide any information regarding whether this individual meets the third criterion. Therefore, such a nuclear pharmacist could qualify as an authorized nuclear pharmacist if that individual has completed a structured educational program that equals or exceeds the requirements of § 35.980(b)(1).

Section 35.981 Training for Experienced Nuclear Pharmacists

Comment. This section was not included in the proposed rule, but has been added to the final rule in response to numerous comments. The comments suggested that the NRC should provide a mechanism for "grandfathering" qualified nuclear pharmacists who are currently working in hospital-based nuclear pharmacies, similar to the mechanism proposed for "grandfathering" qualified individuals who are currently working in commercial nuclear pharmacies.

Response. The Commission agrees with these comments because the "grandfathering" provisions should apply regardless of whether a qualified nuclear pharmacist is currently working in a commercial nuclear pharmacy or a hospital-based nuclear pharmacy. Therefore, this section has been added to the final rule.

III. Discussion of Final Rule Text

This section discusses those provisions of the final rule in which the proposed rule language has been modified. These modifications are either based on public comments or the Commission's identified need to modify

or clarify the rule language. Provisions in which the final rule language remains the same as the proposed rule language will not be discussed in this section. Referring to section V entitled "Text of Final Regulations" may expedite the reader's understanding of this discussion.

Section 32.72 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use Under 10 CFR Part 35

Section 32.72(a)(4)

This paragraph contains one modification of the proposed rule language. The phrase "one label is acceptable to NRC provided that it contains all of the information which NRC requires" has been added at the end of the last sentence of this paragraph. This phrase has been added to clarify that this rule allows licensees to use one label if that label contains all the information specified in this section.

Section 32.72(b)

The proposed rule language has been modified to clarify the intent of this section. These modifications are discussed below.

(1) The phrase "a licensee described by paragraph (a)(2)(iii) or (iv) of this section" has been moved from proposed § 32.72(b)(1) to the introductory phrase of § 32.72(b) to clarify that this phrase applies throughout paragraph (b).

(2) The final rule text of § 32.72(b)(1) is essentially the same as the proposed (b)(1) except that the reference to the definition of "authorized nuclear pharmacist" in Part 35 has been moved to paragraph (b)(2).

(3) A new § 35.72(b)(2) has been added to the final rule to make clear that there are three different ways that an individual may qualify as an authorized nuclear pharmacist.

(4) A new § 35.72(b)(3) has been added to the final rule to make clear that the actions authorized in § 32.72(b)(1) and (2) are permitted in spite of more restrictive language in existing license conditions and to avoid the need for many license amendments in order to implement the Commission's intentions.

(5) The proposed § 32.72(b)(2), which provided criteria for "grandfathering" qualified Part 32 "authorized users," has been redesignated as § 32.72(b)(4). Also, the proposed rule specified that a pharmacist may be "grandfathered" if the individual is identified on a Commission license as an "authorized user" on or before the "effective date" of the rule; this cutoff date has been changed to the publication date of the final rule. This change is needed because the Commission believes that "grandfathering" is only appropriate for those qualified nuclear pharmacists who are "authorized users" on or before the publication date of this final rule.

(6) The proposed § 32.72(b)(3), which requires licensees to provide certain documents, has been redesignated as § 32.72(b)(5). The final rule text in this paragraph has been modified to include several editorial changes, including:

(i) Replacing the phrase "the individual's board certification, the license, or the permit" by the phrase "each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope";

(ii) Replacing the phrase "within 30 days of the date" by the phrase "no later than 30 days after the date"; and

(iii) Adding "pursuant to paragraphs (b)(2)(i) or (b)(2)(iii)" to indicate that a notification is not required by paragraph (b)(2)(ii) because a license amendment is required.

Section 35.2 Definitions

Authorized nuclear pharmacist. During the public comment period, the Commission became aware that the word "currently" is unnecessary in the proposed phrase "Authorized nuclear pharmacist means a pharmacist who is: (1) Currently board certified as a nuclear pharmacist by _____." Therefore, the word, "currently," has been removed in the final rule.

Misadministration. During the public comment period, the Commission became aware of the need to clarify paragraph (4)(iii) of this definition. The existing rule language, "When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose," if interpreted literally, means that a misadministration has occurred only when the calculated weekly administered dose is exactly 30 percent greater than the weekly prescribed dose. The Commission intended for this definition to cover incidents in which there is a difference of 30 percent *or more* between the calculated weekly administered dose and the weekly prescribed dose. To ensure that there is no ambiguity as to the meaning of this provision, it has been reworded and the key phrase in the rule language has been changed from "30 percent greater than" to "30 percent or more." Because this better expresses the intent of the existing rule and is a minor administrative correction, the Commission believes that it can be incorporated in this final rule without having first been included in the proposed rule.

Recordable event. The existing regulatory text of paragraph (5) of this definition of "recordable event" contains the same word structure as paragraph (4)(iii) of the definition of misadministration (discussed above). To ensure that there is no ambiguity as to the meaning of this provision, it has been reworded and the key phrase in the rule language has been changed from "15 percent greater than" to "15 percent or more." Because this better expresses the intent of the existing rule and is a minor administrative correction, the Commission believes that it can be incorporated in this final rule without having first been included in the proposed rule.

Visiting authorized user. During the public comment period, the Commission became aware of the need to delete this definition. This definition is no longer necessary because § 35.27, "Visiting authorized user," in which this definition is applicable is being deleted. Therefore this definition is being removed from the final rule.

Section 35.6 Provisions for Research Involving Human Subjects

This section contains one modification of the proposed rule language. The phrase "in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects" has been added at the end of the last sentence of this section. This phrase has been added to explicitly state that the terms "informed consent" and "IRB approval" have the same meaning ascribed to those terms in the Federal Policy for the Protection of Human Subjects.

Section 35.11 License Required

There is no change between the final rule language and the proposed rule language. However, licensees are reminded that if a licensee intends to increase its possession limit for any byproduct material isotope or add any new byproduct material isotopes, the licensee must first obtain a license amendment.

Section 35.13 License Amendments

There is no change between the final rule language and the proposed rule language in this section. However, the purpose of this discussion is to remind medical use licensees who are not medical institutions that, pursuant to paragraphs (b)(1) through (b)(4) of this section, they must review the necessary credentials and approve or disapprove any individual who is to work as an

authorized user or authorized nuclear pharmacist. In a medical institution, this review and approval must be performed by its Radiation Safety Committee (see § 35.22(b)(2)(ii)).

Section 35.14 Notification

This section contains two editorial changes: (1) the phrase "within 30 days of the date" has been replaced by the phrase "no later than 30 days after the date," and (2) the phrase "the license, or the permit" has been replaced by "the Commission or Agreement state license, or the permit issued by a licensee of broad scope."

Section 35.25 Supervision

There is a modification to the proposed rule in this section. The proposed rule stated that the supervising authorized nuclear pharmacist or physician authorized user must instruct the workers. The final rule allows the instruction to be delegated to other qualified individuals. This change is based on public comments requesting that the instruction of workers be done by the supervising individuals as well as by other qualified individuals. However, the requirement for periodically reviewing the work of supervised individuals remains with the supervising authorized nuclear pharmacist or physician authorized user.

Section 35.50 Possession, Use, Calibration, and Checks of Dose Calibrators

There is an editorial change in this section. The phrase in the proposed rule "over the range of its use between _____ and _____" has been replaced by "over a range from _____ to _____."

Section 35.900 Radiation Safety Officer

Two additional board certifications have been recognized in this section of the final rule.

During the public comment period, the Commission became aware of the need to recognize certifications by the American Osteopathic Board of Nuclear Medicine (AOBNM) and the American Osteopathic Board of Radiology (AOBR). A letter dated August 16, 1990, from Richard E. Cunningham (Director, Division of Industrial and Medical Nuclear Safety, NRC), to Paul J. Chase (Chairman, AOBR and Vice President, AOBNM), stated that the NRC intended to include certifications of (1) AOBR in § 35.900, and (2) AOBNM in §§ 35.900, 35.910, and 35.920 in the next amendment to 10 CFR Part 35. Therefore, the certifications by AOBR and AOBNM have been added to this section of the final rule.

Section 35.910 Training for Uptake, Dilution, and Excretion Studies

Section 35.920 Training for Imaging and Localization Studies

One additional board certification has been recognized in both sections of the final rule.

As discussed in the previous section, the Commission became aware of the need to recognize certification by AOBNM. Therefore, the certification by AOBNM has been added to both sections of the final rule.

Section 35.930 Training for Therapeutic Use of Unsealed Byproduct Material

Two additional board certifications have been recognized in this section of the final rule.

A comment stated that certification by the American Osteopathic Board of Radiology (AOBR) should be recognized in all applicable sections of 10 CFR Part 35. Under the existing regulations, the Commission has recognized AOBR certification in §§ 35.910, 35.920, 35.940, 35.950, and 35.960.

Following receipt of this comment, the Commission requested additional information from AOBR concerning training and certification criteria for therapeutic use of unsealed byproduct material. After reviewing supporting documents provided by the American Osteopathic College of Radiology (AOCR), the Commission has determined that AOBR certification is equivalent to certification by the American Board of Radiology (ABR). Therefore, recognition of certification by AOBR has been added in § 35.930 of this final rule for certification granted after 1984 because all candidates certified by AOBR since 1984 will meet the NRC's training requirements.

During the public comment period, the Commission also became aware of the need to recognize in § 35.930 certification by the Royal College of Physicians and Surgeons of Canada. This is in addition to the recognition reflected in §§ 35.900, 35.910, and 35.920 of the proposed rule. A letter dated June 3, 1992, from John E. Glenn (Chief, Medical, Academic and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, NRC), to Gilles D. Hurteau of the Royal College of Physicians and Surgeons of Canada, stated that certification by the latter is acceptable for approval, among other things, as an authorized user in § 35.300. Therefore, certification by the Royal College of Physicians and Surgeons of Canada has been added to this section of the final rule.

Section 35.981 Training for Experienced Nuclear Pharmacists

This section was not included in the proposed rule, but has been added to the final rule in response to numerous comments. This section has been patterned after the provisions in 10 CFR Part 32 for "grandfathering" an "authorized user."

To "grandfather" an experienced nuclear pharmacist, the licensee needs to apply for a license amendment identifying that individual as an authorized nuclear pharmacist. The licensee must receive the license amendment before allowing that individual to work as an authorized nuclear pharmacist.

A licensee seeking to "grandfather" a nuclear pharmacist must ensure that the individual has completed a structured educational program as specified in § 35.980(b)(1) on or before (the date of publication in the Federal Register) and is currently working as a nuclear pharmacist. However, the individual does not need a preceptor statement (§ 35.980(b)(2)) and the individual's training, specified above, does not need to be within 7 years preceding the date of application (§ 35.972).

Agreement State Compatibility

There were numerous public comments concerning compatibility. The commenters offered a wide range of opinions, from those recommending no compatibility to those favoring identical requirements between Agreement States and the NRC. These comments and NRC's responses will be discussed at the end of this section.

After considering the comments, the Commission has determined that the compatibility levels for the final rule should remain the same as the proposed rule. All definitions contained in §§ 30.4 and 35.2 that are established or modified by this rulemaking are Division 1 levels of compatibility. These definitions must be the same for all NRC and Agreement State licensees so that national consistency can be maintained.

Additionally, §§ 32.72, 35.6, 35.22(b)(2), 35.25, 35.50, 35.52, 35.53, 35.920, 35.972, 35.980, and 35.981 are Division 2 levels of compatibility because requirements at least this stringent are necessary to ensure adequate protection of the public health and safety. The Agreement States will be allowed to establish requirements that are more stringent than the NRC's requirements, but not less stringent.

It would be appropriate for Agreement States to adopt the remaining sections of these revisions to Part 35 in this rulemaking, but it is not necessary to require any degree of compatibility between NRC and the States. Therefore, a Division 3 level of compatibility is appropriate for these sections.

The Commission is currently developing a new policy on Agreement State compatibility. This development will include involvement of the Agreement States and the general public. At the conclusion of this effort, the Commission will implement guidance on the application of adequacy and compatibility and in light of the new guidance will reassess the existing compatibility levels.

The Commission expects Agreement States to adopt rules required to maintain compatibility within 3 years after NRC's rules become effective. However, the States may elect to implement on a temporary basis the requirements contained in this final rule through license conditions prior to promulgation of the rule necessary for compatibility. In the preamble of the notice of the proposed rule, the Commission stated that some Agreement States, faced with administrative and resource constraints, may find the 3-year time period difficult to attain and may prefer that NRC extend flexibility in such cases to allow the States to implement the requirements through license conditions. In the same notice, the Commission requested public comment on permitting Agreement States flexibility in this regard, and if permitted, under what conditions.

The NRC did not receive any comments on implementing requirements through license conditions. Under current policy, the Agreement States have the flexibility to implement the requirements contained in this final rule on a temporary basis through license conditions, until they adopt compatible rules. In addition, this issue will be addressed in the development of a new policy statement on adequacy and compatibility.

There were numerous comments related to Agreement State compatibility. These comments and the NRC's responses are summarized below.

(1) *Comment.* It is inappropriate for the NRC to use the existing policy for compatibility determinations regarding this rulemaking because the NRC is currently considering a new policy.

Response. The Commission must use the existing policy for compatibility determinations regarding all rulemakings until the new policy becomes effective. At that time, the Commission expects that the existing compatibility determinations will be reviewed in light of the new policy.

(2) *Comment.* There is an increasing tendency of NRC to use the term "safety significance" in justifying the NRC's position on compatibility determination. But the question is, "How much significance?"

Response. Under the existing policy the Commission considers the safety significance of a particular requirement, i.e., whether it is necessary to ensure adequate protection of the public health and safety, in determining whether it should be an item of Agreement State compatibility. If it is necessary to ensure adequate protection, the requirement will, at a minimum, be Division 2 level of compatibility. In addition, if the requirement is both necessary for adequate protection and clear communication, it will be a Division 1 level of compatibility. Using these criteria, the Commission has made the findings on compatibility described above. The basic objective of these findings is to ensure that the public receives adequate radiation protection during medical procedures without undue interference in the practices of pharmacy and medicine. The relationship between compatibility and health and safety will be clarified in the new policy on Agreement State compatibility.

(3) *Comment.* Some commenters suggested that Agreement States' requirements should be identical to NRC's requirements. Other commenters suggested that a high degree of consistency between Agreement States and the NRC on medical rules is not necessary.

Response. The Commission believes in some cases, that it is necessary for Agreement States' regulations to be essentially verbatim, i.e., identical, to NRC regulations. In other cases, it is necessary for the Agreement States to adopt the provisions in a consistent although not identical form. As discussed above in the response to comment (2), the Commission has determined which provisions of this rule are a Division 1 level of compatibility. Except for definitions which are a Division 1 level of compatibility, all other provisions of this final rule are either Division 2 or 3 levels of compatibility. Thus, for this final rule, uniformity is not required between Agreement States and the NRC for all provisions.

(4) *Comment.* Medical facilities are essentially fixed facilities with little or no implications for interstate commerce. Where is the justification for the NRC's position?

Response. In the proposed rule, the NRC did not state that the reason for the proposed compatibility levels was due to interstate commerce implications. As stated earlier, the justifications for compatibility are as follows. All definitions contained in §§ 30.4 and 35.2 that are established or modified by this rulemaking are Division 1 levels of compatibility. These definitions must be the same for all NRC and Agreement State licensees so that national consistency can be maintained. Also, certain specific sections are Division 2 levels of compatibility because requirements at least this stringent are necessary to ensure adequate protection of the public health and safety.

(5) *Comment.* The proposed rule stated that all definitions in §§ 30.4 and 35.2 would be Division 1 levels of compatibility. This would include definitions in § 30.4 that do not relate to medical uses and should not be affected by this rulemaking.

Response. The language in the preamble for the proposed rule intended to indicate that all definitions in §§ 30.4 and 35.2 that are established or modified by this rulemaking would be Division 1 levels of compatibility. Levels of compatibility for other definitions in existing §§ 30.4 and 35.2 that are not modified in this rulemaking will remain unchanged. The language in this preamble has been modified to clarify this point.

(6) *Comment.* Based on the State Agreements Program Procedure B.7, all Part 35 items categorized in that procedure are Division 3.

Response. Before the quality management program and misadministration rulemaking became effective, all sections in Part 35 were Division 3 levels of compatibility. However, following that amendment (56 FR 34104; July 25, 1991), the levels of compatibility for Part 35 were modified as follows: The definitions associated with the quality management rule and misadministrations in § 35.2 became Division 1 levels of compatibility; §§ 35.32 and 35.33 became Division 2 levels of compatibility; § 35.8 became a Division 4 level of compatibility; and all other sections of Part 35 remained Division 3 levels of compatibility.

(7) *Comment.* The proposed rule stated that Agreement States are expected to adopt rules required to maintain compatibility within 3 years. Agreement States should be able to adopt this rulemaking in a shorter time.

Response. Some Agreement States may need less time to adopt certain parts of this rulemaking. Other Agreement States may need the full 3 years to adopt the rule because of

constraints on resources. Therefore, the Commission retains the 3-year period for adopting this rule. In reevaluating its compatibility policy, the Commission is considering whether the time can be shortened when demonstrable health and safety considerations require it.

(8) *Comment.* What would happen if an Agreement State fails to adopt requirements that are items of compatibility?

Response. During the periodic review of the Agreement State's program, the NRC would determine whether the State meets the compatibility requirements. If not, the State would be notified that its program must be compatible with the NRC's requirements, and using current procedures a finding of compatibility for the Agreement State program would be withheld. Such a failure, if uncorrected or unjustified, could lead to the loss of the State's status as an Agreement State.

(9) *Comment.* Creating a Division 1 or Division 2 level of compatibility for parts of this rule may cause conflict with State boards of pharmacy and medicine.

Response. The provisions contained in this rulemaking that require a Division 1 or Division 2 level of compatibility are necessary to provide an adequate level of protection of public health and safety from radiological hazards. In addition, the Commission is not aware of any conflicts between these provisions and the requirements of State boards of pharmacy and medicine.

IV. Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this final amendment is not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The final amendment provides greater flexibility for physician authorized users to use byproduct material in the practice of medicine. The final amendment will also incorporate into the regulations the concept of authorized nuclear pharmacists to permit properly qualified pharmacists to prepare radioactive drugs containing byproduct material in the practice of pharmacy.

The final rule will allow physician authorized users greater discretion to prepare and use radioactive drugs containing byproduct material. The final rule will also allow authorized nuclear pharmacists greater discretion to prepare radioactive drugs containing byproduct material. It is expected that there will be no increase in radiation exposure to the public or to the environment beyond the exposures currently resulting from delivering the byproduct material or radiation from byproduct material to patients or human research subjects. The environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the environmental assessment and the finding of no significant impact are available from Anthony N. Tse (see FOR FURTHER INFORMATION CONTACT heading).

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq). These requirements were approved by the Office of Management and Budget, approval numbers 3150–0001 and 3150–0010 for amendments to 10 CFR Parts 32 and 35, respectively.

The reduction in public burden for this collection of information is estimated to be a savings of 408 hours per year for 300 NRC licensees, or an average 1.4 hours per year per licensee, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (T–6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0001, -0010, and -0120), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a final regulatory analysis on this regulation. The analysis examines the benefits and impacts considered by the Commission. No public comments were received on the draft regulatory analysis associated with the proposed rule. The final regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft analysis are available from Anthony N. Tse (see FOR FURTHER INFORMATION CONTACT heading).

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects medical use licensees including some private practice physicians. Some of these licensees would be considered small entities under the NRC's size standards (56 FR 56671; November 6, 1991). The amendments provide greater discretion for physician authorized users to use byproduct material in the practice of medicine. The amendments will also incorporate into the regulations the concept of authorized nuclear pharmacists to allow properly qualified pharmacists greater discretion to prepare (including compound) radioactive drugs containing byproduct material for medical use. This rule is expected to reduce regulatory burdens on medical use licensees, including small entities. No public comments were received related to the regulatory flexibility certification associated with the proposed rule.

Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to this amendment because this amendment does not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1). Therefore, a backfit analysis is not required for this amendment.

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 32

Byproduct material, Criminal Penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553,

the Commission is adopting the following amendments to 10 CFR Parts 30, 32, and 35.

V. Text of Final Regulations

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for Part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, Sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 30.4, the definition of *medical use* is revised to read as follows:

§ 30.4 Definitions.

* * * * *

Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in 10 CFR Part 35.

* * * * *

3. In § 30.8, paragraphs (b) and (c) are revised to read as follows:

§ 30.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 30.9, 30.11, 30.15, 30.19, 30.20, 30.32, 30.34, 30.35, 30.36, 30.37, 30.38, 30.41, 30.50, 30.51, 30.55, and Appendix A.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 30.32, 30.37, and 30.38, NRC Form 313 is approved under control number 3150-0120.

(2) In § 30.36, NRC Form 314 is approved under control number 3150-0028.

§ 30.34 [Amended]

4. Section 30.34 is amended by removing paragraph (c) in its entirety

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

5. The authority citation for Part 32 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

6. In § 32.8, paragraphs (b) and (c) are revised to read as follows:

§ 32.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 32.12, 32.14, 32.15, 32.16, 32.17, 32.18, 32.19, 32.20, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.70, 32.71, 32.72, and 32.74.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 32.11, NRC Form 313 is approved under control number 3150-0120.

7. Section 32.72 is revised to read as follows:

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to Part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33;

(2) The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(ii) Registered or licensed with a state agency as a drug manufacturer;

(iii) Licensed as a pharmacy by a State Board of Pharmacy; or

(iv) Operating as a nuclear pharmacy within a Federal medical institution.

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) A label is affixed to each container of a radioactive drug to be transferred for commercial distribution. The label must include the name of the radioactive drug or its abbreviation, quantity of radioactivity, and date and time of assay. For radioactive drugs with a half life greater than 100 days the time of assay may be omitted. In addition, the label for the syringe or syringe radiation shield must also contain the clinical procedure to be performed or the patient's or the human research subject's name. Furthermore, the label, or the leaflet or brochure that accompanies the radioactive drug, must contain a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the byproduct material to persons licensed to use byproduct material pursuant to 10 CFR 35.100, 35.200, or 35.300, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. The Commission's labeling requirements are independent of requirements of the U.S. Food and Drug Administration (FDA); one label is acceptable to NRC provided that it contains all of the information which NRC requires.

(b) A licensee described by paragraph (a)(2)(iii) or (iv) of this section:

(1) May prepare radioactive drugs for medical use, as defined in 10 CFR 35.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (b)(2) and (b)(3) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.25.

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in 10 CFR 35.2,

(ii) This individual meets the requirements specified in 10 CFR 35.980(b) and 35.972 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (b)(3) of this section.

(3) The actions authorized in paragraphs (b)(1) and (b)(2) of this section are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in 10 CFR 35.2) as an authorized nuclear pharmacist if the

individual is identified as of (the date of publication in the **Federal Register**) as an "authorized user" on a nuclear pharmacy license issued by the Commission under this part.

(5) Shall provide to the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

§ 32.73 [Removed]

8. Section 32.73 is removed.

9. In § 32.303, paragraph (b) is revised to read as follows:

§ 32.303 Criminal penalties.

* * * * *

(b) The regulations in Part 32 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 32.1, 32.2, 32.8, 32.11, 32.14, 32.17, 32.18, 32.22, 32.23, 32.24, 32.26, 32.27, 32.28, 32.51, 32.53, 32.57, 32.61, 32.71, 32.74, 32.301, and 32.303.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

10. The authority citation for Part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

11. In § 35.2, the definition of *visiting authorized user* is removed; the definitions of *authorized nuclear pharmacist* and *pharmacist* are added; and the definitions of *authorized user, medical use, misadministration*—paragraphs (1)(i), (2)(i), (3)(i), (4)(i), (4)(iii), (5)(i), (6)(i), and (6)(ii), *recordable event*—paragraph (5), and *written directive*—the introductory text, are revised to read as follows:

§ 35.2 Definitions.

* * * * *

Authorized nuclear pharmacist means a pharmacist who is:

(1) Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;

(2) Identified as an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or

(3) Identified as an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy.

Authorized user means a physician, dentist, or podiatrist who is:

(1) Board certified by at least one of the boards listed in Paragraph (a) of §§ 35.910, 35.920, 35.930, 35.940, 35.950, or 35.960;

(2) Identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(3) Identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.

* * * * *

Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

* * * * *

Misadministration means the administration of:

(1) * * *

(i) Involving the wrong patient or human research subject, or wrong radiopharmaceutical; or

* * * * *

(2) * * *

(i) Involving the wrong patient or human research subject, wrong radiopharmaceutical, or wrong route of administration; or

* * * * *

(3) * * *

(i) Involving the wrong patient or human research subject, or wrong treatment site; or

* * * * *

(4) * * *

(i) Involving the wrong patient or human research subject, wrong mode of treatment, or wrong treatment site;

* * * * *

(iii) When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

* * * * *

(5) * * *

(i) Involving the wrong patient or human research subject, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

* * * * *

(6) * * *

(i) Involving the wrong patient or human research subject, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the patient or human research subject exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

* * * * *

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

* * * * *

Recordable event means the administration of:

* * * * *

(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

* * * * *

Written directive means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

* * * * *

12. Section 35.6 is added to read as follows:

§ 35.6 Provisions for research involving human subjects.

A licensee may conduct research involving human subjects using byproduct material provided that the

research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

13. Section 35.7 is added to read as follows:

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

14. In § 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.29, 35.31, 35.50, 35.51, 35.52, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, 35.647, 35.980, and 35.981.

* * * * *

15. In § 35.11, paragraph (a) is revised and paragraph (c) is added to read as follows:

§ 35.11 License required.

(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.

* * * * *

(c) An individual may prepare unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.25, unless prohibited by license condition.

16. In § 35.12, paragraph (e) is added to read as follows:

§ 35.12 Application for license, amendment, or renewal.

* * * * *

(e) An applicant that satisfies the requirements specified in 10 CFR 33.13 may apply for a Type A specific license of broad scope.

17. In § 35.13, paragraph (b) is revised to read as follows:

§ 35.13 License amendments.

* * * * *

(b) Before it permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

(1) An authorized user certified by the organizations specified in paragraph (a) of § 35.910, 35.920, 35.930, 35.940, 35.950, or 35.960;

(2) An authorized nuclear pharmacist certified by the organization specified in paragraph (a) of § 35.980;

(3) Identified as an authorized user or an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively; or

(4) Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.

* * * * *

18. Section 35.14 is revised to read as follows:

§ 35.14 Notifications.

(a) A licensee shall provide to the Commission a copy of the board certification, the Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to § 35.13 (b)(1) through (b)(4).

(b) A licensee shall notify the Commission by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

19. Section 35.15 is added to read as follows:

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(a) The provisions of § 35.13(b);

(b) The provisions of § 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;

(c) The provisions of § 35.14(a); and

(d) The provisions of § 35.14(b)(1) for an authorized user or an authorized nuclear pharmacist.

20. In § 35.22, paragraph (b)(2) is revised to read as follows:

§ 35.22 Radiation Safety Committee.

* * * * *

(b) * * *

(2)(i) Review, on the basis of safety and with regard to the training and experience standards in Subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; or

(ii) Review, pursuant to § 35.13 (b)(1) through (b)(4), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

* * * * *

21. In § 35.25, paragraph (b) is redesignated as paragraph (c) and a new paragraph (b) is added to read as follows.

§ 35.25 Supervision.

* * * * *

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(c), shall:

(1) Instruct the supervised individual in the preparation of byproduct material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions given pursuant to paragraph (b)(1) of this section and to comply with the

regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing byproduct material for medical use and the records kept to reflect that work.

* * * * *

§ 35.27 [Removed]

22. Section 35.27 is removed.

23. In § 35.32, paragraphs (a)(2) and (b)(1)(i) are revised to read as follows:

§ 35.32 Quality management program.

(a) * * *

(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

* * * * *

(b) * * *

(1) * * *

(i) A representative sample of patient and human research subject administrations,

* * * * *

24. In § 35.33, paragraphs (a)(2), (a)(3), (a)(4), (b), and (c) are revised to read as follows:

§ 35.33 Notifications, reports, and records of misadministrations.

(a) * * *

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient or the human research subject; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient or the human research subject or the patient's or the human research subject's responsible relative or guardian (this individual will subsequently be referred to as "the patient or human research subject"), and if not, why not, and if the patient or the human research subject was notified, what information was provided to that individual. The report must not include the patient's or the human research subject's name or other information that could lead to identification of the patient or the human research subject.

(3) The licensee shall notify the referring physician and also notify the patient or the human research subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or the human research subject or that, based on medical judgment, telling the patient or the human research subject would be harmful to the patient or the human research subject. The licensee is not required to notify the patient or the human research subject without first consulting the referring physician. If the referring physician or the patient or the human research subject cannot be reached within 24 hours, the licensee shall notify the patient or the human research subject as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient or the human research subject, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient or the human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient or the human research subject by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient or the human research subject, and the patient's or human research subject's referring physician), the patient's or the human research subject's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or human research subjects (or the patient's or the human research subject's responsible relative or guardian).

25. Section 35.49 is revised to read as follows:

§ 35.49 Suppliers for sealed sources or devices for medical use.

A licensee may use for medical use only:

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR Part 30 and 10 CFR 32.74 or the equivalent requirements of an Agreement State; or

(b) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30 or the equivalent requirements of an Agreement State.

26. In § 35.50, paragraphs (a), (b)(3), and (e)(2) through (e)(4) are revised to read as follows:

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A licensee shall possess and use a dose calibrator to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or human research subject.

(b) * * *

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries); and

* * * * *

(e) * * *

(2) For paragraph (b)(2) of this section, the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the identity of the individual performing the test.

(3) For paragraph (b)(3) of this section, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test.

(4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the identity of the individual performing the test.

27. Section 35.52 is added to read as follows:

§ 35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

(a) This section does not apply to unit dosages of alpha- or beta- emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements.

(b) For other than unit dosages obtained pursuant to paragraph (a) of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

28. In § 35.53, the section heading and paragraphs (a), (b), (c)(2), and (c)(3) are revised as follows:

§ 35.53 Measurement of dosages of unsealed byproduct material for medical use.

* * * * *

(a) Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use.

(b) Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements;

(c) * * *

(2) Patient's or human research subject's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries);

* * * * *

29. In § 35.60, paragraphs (b) and (c) are revised to read as follows:

§ 35.60 Syringe shields and labels.

* * * * *

(b) To identify its contents, a licensee shall conspicuously label each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's or the human research subject's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient or human research subject.

30. Section 35.75 is revised to read as follows:

§ 35.75 Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either:

(1) The measured dose rate from the patient or the human research subject is less than 5 millirems per hour at a distance of 1 meter; or

(2) The activity in the patient or the human research subject is less than 30 millicuries.

(b) A licensee may not authorize release from confinement for medical care of any patient or human research subject administered a permanent implant until the measured dose rate from the patient or the human research subject is less than 5 millirems per hour at a distance of 1 meter.

31. Section 35.100 is revised to read as follows:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.

A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

32. Section 35.200 is revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies.

A licensee may use for imaging and localization studies any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

33. Section 35.300 is revised to read as follows:

§ 35.300 Use of unsealed byproduct material for therapeutic administration.

A licensee may use for therapeutic administration any unsealed byproduct material prepared for medical use that is either:

(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

34. In § 35.310, the introductory text of paragraph (a), and paragraphs (a)(1) and (a)(5) are revised to read as follows:

§ 35.310 Safety instruction.

(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter. To satisfy this requirement, the instruction must describe the licensee's procedures for:

(1) Patient or human research subject control;

* * * * *

(5) Notification of the Radiation Safety Officer in case of the patient's or the human research subject's death or medical emergency.

* * * * *

35. In § 35.315, the introductory text of paragraph (a), and paragraphs (a)(2), (a)(3), (a)(5), (a)(6), (a)(7), and (b) are revised to read as follows:

§ 35.315 Safety precautions.

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter, a licensee shall:

* * * * *

(2) Post the patient's or the human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;

(3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the

authorized user after consultation with the Radiation Safety Officer;

* * * * *

(5) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(6) Provide the patient or the human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or the human research subject.

(7) Survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

* * * * *

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

36. Section 35.404 is revised to read as follows:

§ 35.404 Release of patients or human research subjects treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient or human research subject surveys for three years. Each record must include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey.

37. In § 35.406, paragraphs (a), (b), and (c) are revised to read as follows:

§ 35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient or a human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the patient's or the human research subject's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;

(3) The number and activity of sources returned to storage, the patient's or the human research subject's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient or a human research subject the licensee shall make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

* * * * *

38. In § 35.410, the introductory text of paragraph (a), and paragraphs (a)(3) and (a)(5) are revised to read as follows:

§ 35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient or the human research subject undergoing implant therapy. To satisfy this requirement, the instruction must describe:

* * * * *

(3) Procedures for patient or human research subject control;

* * * * *

(5) Procedures for notification of the Radiation Safety Officer if the patient or the human research subject dies or has a medical emergency.

* * * * *

39. In § 35.415, the introductory text of paragraph (a), and paragraphs (a)(1), (a)(2), (a)(3), (a)(5) and (b) are revised to read as follows:

§ 35.415 Safety precautions.

(a) For each patient or human research subject receiving implant therapy, a licensee shall:

(1) Not quarter the patient or the human research subject in the same room with an individual who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of § 20.105(b) or, for licensees implementing the provisions of §§ 20.1001–20.2401, through § 20.1301(a) of this chapter at a distance of 1 meter from the implant;

(2) Post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and

* * * * *

(5) Provide the patient or the human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the individual if the individual was administered a permanent implant.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

40. In § 35.610, paragraph (a)(1) is revised to read as follows:

§ 35.610 Safety instruction.

(a) * * *

(1) The procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;

* * * * *

41. In § 35.615, paragraphs (d)(3) and (e) are revised to read as follows:

§ 35.615 Safety precautions.

* * * * *

(d) * * *

(3) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

* * * * *

(e) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the

teletherapy unit console during irradiation.

42. In § 35.900, paragraphs (a)(4) and (a)(5) are revised and paragraphs (a)(6) through (a)(9) are added to read as follows:

§ 35.900 Radiation Safety Officer.

* * * * *

(a) * * *

(4) American Board of Science in Nuclear Medicine;

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine; or

* * * * *

43. In § 35.910, paragraph (a)(3) is revised, paragraphs (a)(4) and (a)(5) are added, and paragraphs (b)(2)(i), (b)(2)(iii), and (b)(2)(v) are revised to read as follows:

§ 35.910 Training for uptake, dilution, and excretion studies.

* * * * *

(a) * * *

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) * * *

(2) * * *

(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

* * * * *

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

* * * * *

(v) Patient or human research subject followup; or

* * * * *

44. In § 35.920, paragraphs (a)(2) and (a)(3) are revised, paragraphs (a)(4) and (a)(5) are added, and paragraphs (b)(2)(iii), (b)(3)(i), (b)(3)(iii), and (b)(3)(v) are revised to read as follows:

§ 35.920 Training for imaging and localization studies.

* * * * *

(a) * * *

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) * * *

(2) * * *

(iii) Calculating and safely preparing patient or human research subject dosages;

* * * * *

(3) * * *

(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

* * * * *

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

* * * * *

(v) Patient or human research subject followup; or

* * * * *

45. In § 35.930, the section heading and paragraphs (a)(1) and (a)(2) are revised and paragraphs (a)(3) and (a)(4) are added to read as follows:

§ 35.930 Training for therapeutic use of unsealed byproduct material.

* * * * *

(a) * * *

(1) The American Board of Nuclear Medicine;

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

(3) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(4) The American Osteopathic Board of Radiology after 1984; or

* * * * *

46. In § 35.940, paragraph (a)(1) is revised to read as follows:

§ 35.940 Training for use of brachytherapy sources.

* * * * *

(a) * * *

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

* * * * *

47. In § 35.950, paragraphs (a)(1) and (a)(2) are revised and paragraph (a)(4) is added to read as follows:

§ 35.950 Training for use of sealed sources for diagnosis.

* * * * *

(a) * * *

(1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine;

* * * * *

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

* * * * *

48. In § 35.960, paragraphs (a)(1) and (b)(3)(iii) are revised to read as follows:

§ 35.960 Training for teletherapy.

* * * * *

(a) * * *

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

* * * * *

(b) * * *

(3) * * *

(iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

* * * * *

49. In § 35.961, paragraph (b) is redesignated as paragraph (c) and a new paragraph (b) is added to read as follows:

§ 35.961 Training for teletherapy physicist.

* * * * *

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

* * * * *

50. Section 35.972 is revised to read as follows:

§ 35.972 Recentness of training.

The training and experience specified in this subpart must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

51. Section 35.980 is added to read as follows:

§ 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised experience in a nuclear pharmacy involving the following:

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

52. Section 35.981 is added to read as follows:

§ 35.981 Training for experienced nuclear pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in § 35.980(b)(1) before (the date of publication in the **Federal Register**) and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (§ 35.980(b)(2)) and recentness of training (§ 35.972) to qualify as an authorized nuclear pharmacist.

53. In § 35.991, paragraph (b) is revised to read as follows:

§ 35.991 Criminal penalties.

* * * * *

(b) The regulations in Part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.57, 35.100, 35.600, 35.901, 35.970, 35.971, 35.990, 35.991, and 35.999.

Dated at Rockville, Maryland, this 25th day of November, 1994.

For the Nuclear Regulatory Commission.

John C. Hoyle

Acting Secretary of the Commission.

[FR Doc. 94-29525 Filed 12-1-94; 8:45 am]

BILLING CODE 7590-01-P

FEDERAL RESERVE SYSTEM

12 CFR Part 205

[Regulation E; Docket No. R-0859]

Electronic Fund Transfers

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Interim rule with request for comments.

SUMMARY: The Board is publishing an interim rule amending Regulation E (Electronic Fund Transfers). The amendment eliminates the requirement that an electronic terminal receipt disclose a number or code that *uniquely* identifies the consumer, the consumer's account, or the access device. This requirement currently poses a significant security risk for consumers and financial institutions by making information accessible to criminals that they then use to withdraw funds from consumers' accounts. The Board has adopted an interim rule that deletes the requirement for a unique identification, thus enabling institutions to truncate card or account numbers. The Board seeks public comment on the interim rule, which the Board will adopt in final following the close of the comment period.

DATES: Interim rule effective December 1, 1994; comments must be received on or before February 1, 1995.

ADDRESSES: Comments should refer to Docket No. R-0859 and be sent to William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. They may also be delivered to Room B-2222 of the Eccles Building between 8:45 a.m. and 5:15 p.m. weekdays, or to the guard station in the Eccles Building courtyard on 20th Street, N.W. (between Constitution Avenue and C Street) at any time. Comments received will be available for inspection in Room MP-500 of the Martin Building between 9:00 a.m. and 5:00 p.m. weekdays, except as provided in 12 CFR 261.8 of the Board's rules regarding availability of information.

FOR FURTHER INFORMATION CONTACT: Jane Jensen Gell or Kyung Cho-Miller, Staff Attorneys, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, Washington, DC 20551, at (202) 452-2412 or (202) 452-3667. For the hearing impaired *only*, contact Dorothea Thompson, Telecommunications Device for the Deaf (TDD), at (202) 452-3544.

SUPPLEMENTARY INFORMATION:

I. Background

The Board's Regulation E implements the Electronic Fund Transfer Act (EFTA). The EFTA provides a basic framework establishing the rights, liabilities, and responsibilities of participants in electronic fund transfer (EFT) systems. Types of transfers covered by the act and regulation include transfers initiated through an automated teller machine (ATM), point-of-sale terminal, automated clearinghouse, telephone bill-payment system, or home banking program. Regulation E establishes restrictions on the unsolicited issuance of ATM cards and other access devices; requires disclosure of terms and conditions of an EFT service; calls for documentation of EFTs through terminal receipts and periodic account statements; provides limitations on consumer liability for unauthorized transfers; and establishes procedures for error resolution.

II. Summary of Amendment

Section 205.9—Documentation of Transfers

Paragraph (a)—Receipts at Electronic Terminals

Under the EFTA, when a consumer initiates an EFT at an electronic terminal, the financial institution must make a written receipt available to the consumer. The receipt must identify in some way the consumer's account with the financial institution from or to which funds are transferred.

Under the Board's Regulation E, institutions can comply with this identification requirement by including a number or code on the receipt that identifies the access device used to initiate the transfer, the consumer initiating the transaction, or the consumer's accounts. To ensure adequate identification, the Board's regulation specifies that the number or code should be "unique."

This identification requirement was adopted in 1979, and over the years many financial institutions have met the requirement by disclosing consumers' card or account numbers on the receipt; until recently, doing so did not appear

12/02/94

AD 69-2
PDR

Regulatory Analysis
For Final Rulemaking Entitled
"Preparation, Transfer for Commercial Distribution,
and Use of Byproduct Material for Medical Use"
10 CFR Parts 30, 32, and 35

1. Background

1.1 Statement of the Problem

A petition for rulemaking (PRM-35-9) concerning the medical use of byproduct material was submitted jointly by the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM). The petition requested that the NRC amend its regulations to fully recognize the role of licensed nuclear pharmacists and physicians. The petition addressed issues related to the preparation and use of radioactive drugs containing byproduct material for diagnostic, therapeutic, or research purposes. In addition, certain portions of the existing regulations in Parts 32 and 35 need to be updated, clarified, or simplified. This final rulemaking has been prepared in response to the petition and to provide miscellaneous amendments to update or clarify the existing regulations.

1.2 NRC's Policy Statement on the Medical Use of Radioisotopes

In a policy statement published on February 9, 1979 (44 FR 8242), entitled "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," the NRC stated:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

In conformance with this policy, the Commission is eliminating certain restrictions in the NRC regulations regarding the preparation and use of byproduct material for medical use. In addition, the Commission will provide the authority to licensees to conduct research involving human subjects and to use radiolabeled biologics. The Commission believes that these restrictions can be eliminated without compromising the level of protection of public health and safety against radiological hazards. The Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients and recognizes that the nuclear pharmacists have the primary responsibility for the preparation of radioactive drugs. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians and pharmacists will make decisions that are in the best interest of their patients. Furthermore, the pharmacological aspects of radioactive drugs, including drug safety and efficacy, are regulated by the U.S. Food and Drug Administration (FDA).

1.3 Earlier NRC Actions

Following receipt of the petition, the NRC, in consultation with the FDA, determined that some issues of the petition should be addressed promptly. On August 23, 1990 (55 FR 34513), the Commission published an Interim Final Rule to allow, for a period of 3 years, the use of therapeutic radiopharmaceuticals for indications not listed in the package insert and to allow departures from the manufacturer's instructions for preparing diagnostic radiopharmaceuticals using radionuclide generators and reagent kits, provided that certain recordkeeping requirements were met. Based on the records collected from the affected licensees, both the NRC and FDA staff agreed that the major trends in departures that may be identified by the recordkeeping are already discernible and collecting additional data is unnecessary. On October 2, 1992 (57 FR 45566), the NRC published a rule eliminating the recordkeeping requirements.

In a parallel effort, the NRC continued to work on the remaining issues in the petition. On August 7, 1991, the NRC conducted a workshop in Rosemont, Illinois, presenting strawman language on the training and experience criteria for authorized nuclear pharmacists to representatives of the following organizations: Board of Pharmaceutical Specialties, American Board of Science in Nuclear Medicine, National Association of Boards of Pharmacy, Committee on Radionuclides and Radiopharmaceuticals of the U.S. Council for Energy Awareness, American Pharmaceutical Association, American Society of Hospital Pharmacists, and three graduate schools of pharmacy. Subsequently, the NRC also discussed the proposed resolution of these issues in meetings with the FDA, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), and the Agreement States.

The Commission published proposed amendments in the Federal Register on June 17, 1993 (58 FR 33396) and provided a 120-day public comment period. About 2,500 copies of the notice of the proposed rulemaking were mailed to all applicable NRC licensees, Agreement State and Non-Agreement State agencies, and other interested groups. The NRC received 284 comment letters in response to the proposed rule. There were 280 letters in support of the proposed rule, 1 letter in opposition to the proposed rule, and 3 letters provided comments without specifically indicating support for or opposition to the proposed rule.

In the preamble of the proposed rule, the Commission stated that a draft regulatory analysis was available and requested public comments. The Commission did not receive any public comments on the draft regulatory analysis.

2. Objectives

The objective of this final rulemaking is to grant the petition and to eliminate certain restrictions in NRC's regulations regarding the medical use of byproduct material without compromising the level of protection of public health and safety against radiological hazards.

Specifically, among other things, the final rule will incorporate into NRC's regulations the concept of authorized nuclear pharmacists to allow properly qualified pharmacists greater discretion to prepare (including

compound) radioactive drugs containing byproduct material. Also, the final rule will allow physician authorized users greater discretion to prepare and use radioactive drugs containing byproduct material, the use of byproduct material in research involving human subjects, and the use of radiolabeled biologics containing byproduct material.

In addition, the final rule also contains other miscellaneous and conforming amendments necessary to update or clarify the current regulations.

3. ALTERNATIVES

Two alternatives have been considered for the petition: maintain the status quo or grant the petition.

The first alternative would continue to restrict physicians and pharmacists in the medical use of byproduct material. This alternative would continue to require NRC medical use licensees to meet the current prescriptive regulations which restrict the activities of nuclear physicians in the preparation and use of radioactive drugs. In addition, this alternative would continue to restrict unduly the activities of nuclear pharmacists in the preparation of radioactive drugs when an acceptable alternative exists. Therefore, this alternative was not considered further.

The second alternative, promulgation of a final rule to grant the petition, will provide greater flexibility for physician authorized users to use byproduct material in the practice of medicine. The final amendments will also incorporate into the regulations the concept of authorized nuclear pharmacists to allow properly qualified pharmacists to prepare (including compound) radioactive drugs containing byproduct material. The Commission believes that granting this petition will eliminate certain restrictions regarding the medical use of byproduct material without compromising the level of protection of public health and safety against radiological hazards.

4. Brief Descriptions of the Final Amendments

In response to the petition for rulemaking, the Commission is amending its regulations to:

1. Allow physician authorized users to use therapeutic radioactive drugs containing byproduct material for indications or methods of administration not listed in the FDA-approved package insert;

2. Allow physician authorized users to use radioactive drugs containing byproduct material for research involving human subjects;

3. Allow physician authorized users to use radiolabeled biologics containing byproduct material;

4. Allow medical use licensees and commercial nuclear pharmacies to depart from the manufacturer's instructions for preparing radioactive drugs using radionuclide generators and reagent kits;

5. Allow medical use licensees and commercial nuclear pharmacies to compound radioactive drugs using byproduct material;

6. Delete the existing regulations related to the nonradioactive reagent kits; and

7. Clarify regulatory requirements for specific licenses of broad scope.

Table 1 summarizes the requests made in the petition and the Commission's responses.

5. ESTIMATION OF COST IMPACT

5.1 GENERAL DISCUSSION

The NRC has about 2,000 medical use licensees (licensed under Part 35) and about 50 licensees who manufacture or prepare radioactive drugs (licensed under Part 32). Agreement States have approximately twice the NRC's licensees mentioned above. All definitions contained in §§ 30.4 and 35.2 that are established or modified by this rulemaking are Division 1 levels of compatibility. Sections 32.72, 35.6, 35.22(b)(2), 35.25, 35.50, 35.52, 35.53, 35.920, 35.972, 35.980, and 35.981 are Division 2 levels of compatibility; and the remaining sections in Part 35 in this rulemaking will be Division 3 levels of compatibility.

In addition to the rule, one existing and two draft regulatory guides have been revised to incorporate the provisions of the final rule. These

Table 1

Summary of Requests in the Petition and the Commission's Responses

Request	Response
Permit authorized users to use radiopharmaceuticals for therapeutic uses not covered in the package insert.	Allow physician authorized users who are qualified for therapeutic administration to use radioactive drugs for therapeutic uses not covered in the package insert.
Permit authorized users to use radioactive drugs for research involving human subjects.	Allow physician authorized users to use radioactive drugs for research provided that human research subjects are protected.
Permit authorized users to use radiolabeled biologics.	Allow physician authorized users to use radiolabeled biologics provided that dosages of alpha- or beta-emitting radionuclides are measured.
Permit medical use licensees and pharmacies to depart from package inserts when using generators and kits.	Allow physician authorized users and authorized nuclear pharmacists who meet certain training and experience criteria to depart from package inserts when using generators and kits.
Permit medical use licensees and pharmacies to use byproduct material to compound radioactive drugs.	Allow physician authorized users and authorized nuclear pharmacists who meet certain training and experience criteria to prepare (including compound) radioactive drugs.
Permit nuclear pharmacists to prepare reagent kits.	Delete NRC regulations on reagent kits which do not contain byproduct material. Thus, nuclear pharmacists would be able to prepare reagent kits under applicable law.
Clarify requirements on licenses of broad scope.	Clarify the requirements by adding exemptions in Part 35.

revisions do not impose new requirements. Thus, there will be no additional cost impact associated with the revisions of the regulatory guides.

The cost estimates shown below are for affected NRC licensees only. Therefore, the total cost impacts (i.e., for NRC and Agreement State licensees) associated with this final rule will be approximately 3 times the cost to the affected NRC licensees.

The cost estimates are based on the following:

- Fee per license amendment — Part 32: $490; Part 35: $500
- Unit labor costs (unloaded)

For licensee staff - Physician*	$85/hour
- Scientific staff* (e.g. nuclear pharmacists)	$50/hour
- Technical staff* (e.g. medical technologists)	$30/hour
- Clerical staff	$15/hour
For Agreement State staff*	$50/hour

* Includes prorated amounts for clerical staff.

5.2 IMPACTS ON AFFECTED NRC LICENSEES

Each section of the final rule has been evaluated in terms of the cost impact (i.e., increase, decrease, or no change as compared to the cost under existing situations) on affected licensees. In calculating the cost impacts, the cost savings are expressed as positive (+) values and the cost increases as negative (-) values. The cost impact of each section of the final rule is discussed below except for those sections that obviously have no cost impacts. Table 2 is a summary of the impact on affected licensees for each section.

Table 2

Summary of Impacts on NRC Licensees

Final Section No.	No. of Amend., permission, or Record, etc./yr	Hours	$/hr	Fee*	Impact/yr Savings: + Costs: -
Part 30					
30.4	No cost (See footnote 1)				
30.34(i)	No cost (See 5.2.1 of this analysis)				
Part 32					
32.72(a)	No cost (See footnote 2)				
32.72(b)	20 license amendments eliminated	4 hours	$50	$490	+ $13,800
	50 license amendments eliminated	2 hours	$50	$490	+ $29,500
	50 notifications required	1/2 hour	$30	----	- $750
32.72(c)	No cost (See 5.2.1 of this analysis)				
32.72(d)	No cost (See footnote 3)				
[32.73]	1 license application eliminated	32 hours	$50	$3,500	+ $5,100
32.74	No cost (See footnote 3)				

* The fees are based on current fees (FY 1993). The fees may change for other fiscal years.

Table 2 (Continued)

Summary of Impacts on NRC Licensees

Final Section No.	No. of Amend., permission, or Record, etc./yr	Hours	$/hr	Fee*	Impact/yr Savings: + Costs: -
Part 35					
35.2	No cost (See footnote 1)				
35.6	2 license amendments required	8 hours	$85	$500	- $2,360
35.7	No cost (See footnote 3)				
35.8	No cost (See footnote 2)				
35.11	No cost (See footnote 3)				
35.12	No cost (See footnote 3)				
35.13	200 license amendments eliminated	2 hours	$50	$500	+ $120,000
	10 license amendments required	2 hours	$50	$500	- $6,000
35.14	220 notifications required	1/2 hour	$30	----	- $3,300
35.15	No cost (See footnote 2)				
35.22(b)(2)	No cost (See footnote 2)				
35.25	No cost (See footnote 2)				
[35.27]	100 records eliminated	1/6 hour	$15	----	+ $250
35.49	No cost (See footnote 4)				
35.50	No cost (See footnote 3)				
35.52	No cost (See 5.2.3 of this analysis)				

Table 2 (Continued)

Summary of Impacts on NRC Licensees

Final Section No.	No. of Amend., permission, or Record, etc./yr	Hours	$/hr	Fee*	Impact/yr Savings: + Costs: -
35.53	No cost (See footnote 2)				
35.100 to 35.300	20 license amendments eliminated	2 hours	$50	$500	+ $12,000
35.610 to 35.972	No cost (See footnote 2)				
35.980	20 certifications required	1 hour	$50	----	- $1,000
35.981	5 license amendments required	2 hours	$50	$500	- $3,000
Subtotal				Savings	+ $180,650
				Costs	- $ 16,410
Savings (for NRC licensees)					+ $164,240
Total Savings (for NRC and Agreement State licensees)					+ $492,720

Footnotes:

1. This is a definition, thus no cost impact.

2. This is a clarification or update which will not substantively change the current practice.

3. This is to provide a reminder to licensees, to grandfather an existing situation, or to conform with changes made in other sections or chapters.

4. These requirements or a portion of the existing requirements are moved to other sections.

5.2.1 PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

§ 30.34 Terms and conditions of licenses.

The final amendment will delete paragraph § 30.34(i) in its entirety. Under the existing paragraph, licensees are permitted to depart from FDA-approved package inserts. Under the final rule, this permission will be moved to Part 32 for commercial nuclear pharmacies and to Part 35 for medicaluse licensees. Therefore, there will be no cost impact associated with this final amendment.

5.2.2 PART 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.

§ 32.72(b)

(1) Section 32.72(b) will allow commercial nuclear pharmacies to depart from FDA-approved package inserts and to compound radioactive drugs, without obtaining a license amendment from the NRC. Therefore, a cost saving is expected due to the elimination of these license amendments.

Assuming 20 amendments requesting departures or compounding would be eliminated per year and 4 hours of scientific staff's time would be avoided for preparing an application for a license amendment, the cost saving is estimated to be:

20 amend/yr x (4 hrs/amend x $50/hr + $490 fee/amend) = + $13,800/yr.

(2) This paragraph will allow commercial nuclear pharmacies to permit an individual to work as an authorized nuclear pharmacist, without obtaining a license amendment from the NRC, if the individual is: (1) certified by the Board of Pharmaceutical Specialties; (2) listed on a Commission or an Agreement State license; or (3) listed on a permit issued by a specific

licensee of broad scope as an authorized nuclear pharmacist. This provision will eliminate a current licensing requirement that requires a licensee to obtain a license amendment from the NRC before permitting an "authorized user" to work.

Assuming 50 amendments requesting to add the names of the "authorized users" would be eliminated per year and 2 hours of scientific staff's time would be avoided for preparing an application for amendment, the cost saving is estimated to be:

50 amend/yr x (2 hr/amend x $50/hr + $490 fee/amend) = + $29,500/yr.

(3) This paragraph will require licensees to provide to the NRC a copy of the individual's board certification, the license, or the permit, and the state pharmacy licensure or registration, respectively, for each individual no later than 30 days after the date that the licensee permits, pursuant to this section, the individual to work as an authorized nuclear pharmacist. Therefore, a cost increase is expected due to this notification requirement.

Assuming 50 notifications would be required per year and 1/2 hour of technical staff's time would be needed for preparing a notification, the cost increase is estimated to be:

50 notifications/yr x 1/2 hr/notification x $30/hr = - $750/yr.

§ 32.72(c)

This paragraph is added to clarify that Part 32 licensees measure and record dosages of radioactive drugs, including those containing alpha- or beta-emitting radionuclides, before transferring these drugs to a medical use licensee. Currently, these licensees already possess measurement instrumentation, perform the measurements, and record the dosages to provide information required under existing § 32.72(a)(4)(i). Therefore, there will be no cost impact associated with this final amendment.

§ 32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material.

The section will be deleted in its entirety. This section requires that a licensee shall obtain a specific license from the NRC before the licensee may manufacture or distribute radionuclide generators containing byproduct material or reagent kits. Under the final rule, the existing requirements related to radionuclide generators will be moved to § 32.72. However, the existing requirements related to these reagent kits will be deleted because they do not contain byproduct material. Therefore, a cost saving is expected because the elimination of the application for a license to manufacture or distribute these reagent kits.

The fee for NRC's review of an application to manufacture and distribute a new type of reagent kit is $3,500 per application. Assuming 1 application would be eliminated per year and 32 hours scientific staff's time would be avoided by the licensee to prepare the application, the cost saving would be: 1 application/yr x (32 hrs/appl x $50/hr + $3,500 fee/appl) = + $5,100/yr.

5.2.3 PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL

§ 35.6 Provisions for research involving human subjects.

This section will allow licensees to conduct research using byproduct material involving human subjects provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Thus, a cost increase is expected. However, the NRC believes that most human research involving byproduct material is currently conducted, funded, supported, or regulated by another Federal agency.

Assuming 2 license amendments would be needed per year and 8 hours of physician's time would be needed to prepare an application for amendment, the cost increase would be:

2 amend/yr x (8 hr/amend x $85/hr + $500 fee/amend) = - $2,360/yr.

§ 35.13 License amendments

(1) Paragraph (b) of this section will permit medical use licenses to allow an individual to work as an authorized user, without submitting a license amendment to the NRC, if the physician authorized user is: (a) certified by the appropriate certification boards; (b) listed on a Commission or Agreement State license; or (c) listed on a permit of a Commission or Agreement State specific licensee of broad scope. Under current regulations, a license amendment must be obtained before the individual may work as an authorized user (except for a visiting authorized user). Thus, a cost saving is expected due to the elimination of these license amendments.

Assuming 200 license amendments would be eliminated per year and 2 hours of scientific staff's time would be avoided for preparing an application for amendment, the cost saving would be:

200 amend/yr x (2 hr/amend x $50/hr + $460 fee/amend) = + $112,000/yr.

(2) This paragraph will permit medical use licenses to allow an individual to work as an authorized nuclear pharmacist, without submitting a license amendment to the NRC, if the authorized nuclear pharmacist is: (a) certified by the certification board; (b) listed on a Commission or Agreement State license; or (c) listed on a permit of a Commission or Agreement State specific licensee of broad scope.

However, if the individual does not meet the criteria stated above, a license amendment must be obtained by the licensee before the individual can work as an authorized nuclear pharmacist. Thus, a cost increase is expected due to the requirement for these license amendments.

Assuming 10 license amendments would be required per year and 2 hours of scientific staff's time would be needed for preparing an application for amendment, the cost increase would be:

10 amend/yr x (2 hr/amend x $50/hr + $460 fee/amend) = - $5,600/yr

§ 35.14 Notifications.

In addition to the existing notification requirement, the NRC is amending this section to require specific licensees of limited scope to submit a copy of an individual's board certification, the license, or the permit as discussed in § 35.13. Thus, a cost increase is expected.

Assuming 220 notifications would be needed (200 notifications for authorized users and 20 notifications for authorized nuclear pharmacists) and 1/2 hour of technical staff's time would be needed for preparing each notification, the cost increase would be:

220 notification/yr x 1/2 hr/notification x $30/hr = - $3,300/yr.

§ 35.27 Visiting authorized user.

The NRC is deleting this section because the concept of a visiting authorized user will no longer be necessary. Since a recordkeeping requirement in the existing section will also be eliminated, a cost saving is expected.

Assuming 100 records per year would be eliminated and 10 minutes of clerical staff's time would be avoided for each record, the cost saving would be:

100 records/yr x 1/6 hr x $15/hr = + $250/yr.

§ 35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radioactive drugs.

This paragraph is new and will require Part 35 licensees to possess instrumentation to measure the radioactivity of alpha- or beta-emitting radioactive drugs, except for unit doses obtained from manufacturers or commercial nuclear pharmacies. Most alpha- or beta-emitting radionuclides are used in radiolabeled biologics which are still under new drug investigation.

Under current practice, licensees preparing radiolabeled biologics containing alpha- or beta-emitters in their own facilities or purchase qualities of these radiolabeled biologics from manufacturers or commercial

nuclear pharmacies other than unit doses already have instrumentations to measure the dosages. In addition, licensees who purchase only unit doses will be exempt from this section. Therefore, no cost impact is expected.

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.
§ 35.200 Use of unsealed byproduct material for imaging and localization studies.
§ 35.300 Use of unsealed byproduct material for therapeutic administration.

The final amendments in these three sections will allow medical use licensees to compound radioactive drugs using byproduct material without obtaining specific license amendments. Therefore, a cost saving is expected. Departures from FDA-approved package inserts and manufacturers' instructions are already permitted under the Interim Final Rule.

Assuming 20 license amendments per year would be eliminated and 2 hours of scientific staff's time would be avoided to prepare each application, the cost savings would be:

20 amend/yr x (2 hr/amend x $50/hr + $460 fee/amend) = + $11,200/yr.

§ 35.980 Training for an authorized nuclear pharmacist.

This section will require authorized nuclear pharmacists to meet the training and experience criteria. Because the criteria specified in this section are nearly identical to those in the current licensing guidance, there will be no cost impact on implement this section, with an exception of requiring a written certification from preceptors. Thus, a cost increase is expected.

Assuming 20 certifications would be written per year and 1 hour of scientific staff's time would be needed to complete each certification, the cost increase would be:

20 certification/yr x 1 hr/certification x $50/hr = - $1,000/yr.

§ 35.981 Training for experienced nuclear pharmacists.

This section is being added to the final rule in response to public comments. A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. Because the criteria specified in this section are nearly identical to those in the current licensing guidance, there will be no cost impact on implement this section, with an exception of requiring a license amendment. Thus, a cost increase is expected.

Assuming 5 license amendments would be required per year and 2 hours of scientific staff's time would be needed for preparing an application for amendment, the cost increase would be:

5 amend/yr x (2 hr/amend x $50/hr + $460 fee/amend) = - $2,800/yr.

Total impacts on affected NRC licensees

The cost impact on affected NRC licensees is estimated to be a saving of $156,220 per year (See Table 2).

5.3 IMPACTS ON AFFECTED AGREEMENT STATES LICENSEES

Since Agreement States have approximately twice the NRC's licensees, the impacts for Agreement State licensees associated with this final rule will be approximately twice the impact on the affected NRC licensees. Therefore, the savings for Agreement State licensees will be:

2 x $156,220/yr = + $312,440/yr.

5.4 TOTAL IMPACT ON AFFECTED LICENSEES

The impact on both the NRC licensees and Agreement State licensees will be a savings of

$156,220/yr + $312,440/yr = $468,660/yr.

5.4 COST IMPACT ON NRC

The predominant factor affecting the NRC's operating costs as a result of this final action is the decreased number of license amendments which will no longer need to be processed by the NRC. However, this impact is already addressed in the cost impact on the licensees and is included as the change in fees charged to the licensees.

5.5 IMPACT ON AGREEMENT STATES

Since the requirements contained in this final rulemaking will be a matter of compatibility for the Agreement States, each Agreement State will be required to adopt certain sections of the final rule. The impact on the Agreement States will be associated with the adoption of certain sections of the final rule into their State regulations.

The impact for each Agreement State may be estimated as follows:

o	Draft a final rule	40 hours
o	Review by an Advisory Committee	8 hours
o	Send the final rule to NRC for review	4 hours
o	Prepare a final rule	20 hours
	Impact for an Agreement State	72 hours

Since there are 29 Agreement States, the total impact on the Agreement States to incorporate certain sections of the final rule is estimated to be: 29 Agreement State x 72 hrs/Agreement State x $50/hr = - $104,400.

6. BENEFITS

This final rule will benefit the public by permitting medical use licensees to increase the scope of the applications of radioactive drugs and to increase efficiencies in the preparation and use of radioactive drugs. Specifically, this final rule will provide physician authorized users greater flexibility in the medical use of byproduct material. Similarly, the final rule will permit qualified nuclear pharmacists to use byproduct material to prepare radioactive drugs. Even though the final rule will eliminate certain

restrictions related to the medical use of by byproduct material, the NRC believes that additional safeguards against radiological hazards are included in the final rule that will continue to ensure adequate protection of public health and safety.

7. DECISION RATIONALE

Based on the above analysis, NRC believes that the final rule will provide physician authorized users with greater flexibility to use and will allow authorized nuclear pharmacists to prepare radioactive drugs containing byproduct material. The NRC believes that additional safeguards against radiological hazards are included in the final amendments that will continue to ensure adequate protection of public health and safety. Therefore, the NRC is adopting the final rule.

12/02/94

AD 69-2
PDR

ENVIRONMENTAL ASSESSMENT FOR FINAL AMENDMENTS TO 10 CFR PARTS 30, 32, AND 35, "PREPARATION, TRANSFER FOR COMMERCIAL DISTRIBUTION, AND USE OF BYPRODUCT MATERIAL FOR MEDICAL USE"; FINDING OF NO SIGNIFICANT IMPACT

1. Introduction

The Nuclear Regulatory Commission (NRC) is amending its regulations for the medical use of byproduct material. This action is necessary to respond to a petition for rulemaking and to fully recognize the role of licensed nuclear pharmacists and physicians. The petition for rulemaking (PRM-35-9) was submitted by the American College of Nuclear Physicians and the Society of Nuclear Medicine.

The Commission published a proposed amendments in the Federal Register on June 17, 1993 (58 FR 33396) and provided a 120-day public comment period. About 2,500 copies of the notice of the proposed rulemaking were mailed to all applicable NRC licensees, Agreement State and Non-Agreement State agencies, and other interested groups. The NRC received 284 comment letters in response to the proposed rule. There were 280 letters in support of the proposed rule, 1 letter in opposition to the proposed rule, and 3 letters provided comments without specifically indicating support for or opposition to the proposed rule.

In the preamble of the proposed rule, the Commission stated that a draft environmental assessment and finding or no significant impact was available and requested public comments. The Commission did not receive any public comments on the draft environmental assessment.

The final rule is intended to provide greater flexibility for authorized user physicians to prepare and use radioactive drugs containing byproduct material. The final rule will also incorporate into the regulation the concept of authorized nuclear pharmacists to allow properly qualified pharmacists greater discretion to prepare radioactive drugs containing byproduct material.

The major features of the final amendments include: (1) allowing medical use licensees to depart from the U.S. Food and Drug Administration (FDA) approved package insert instructions regarding the preparation and use

of radioactive drugs; (2) creating the concept of an "authorized nuclear pharmacist" and specifying training and experience requirements; (3) allowing authorized nuclear pharmacists and physician authorized users to use byproduct material to prepare radioactive drugs; (4) allowing the use of byproduct material in research involving human subjects; and (5) allowing the use of radiolabeled biologics.

2. Need for the Amendment: Rejection of the No Action Alternative

The final amendments have been developed to grant the petition for rulemaking. The Commission recognizes that physicians have the primary responsibility for the diagnosis and treatment of their patients, and recognizes that the nuclear pharmacists have the primary responsibility for the preparation of radioactive drugs. The Commission's regulations are predicated on the assumption that properly trained and adequately informed physicians and pharmacists will make decisions that are in the best interest of their patients. Furthermore, the pharmacological aspects of radioactive drugs, including drug safety and efficacy, are regulated by the FDA. Therefore, the final amendments will allow physician authorized users greater discretion in the medical use of byproduct material, and allow authorized user physicians and authorized nuclear pharmacists greater discretion to prepare radioactive drugs containing byproduct material.

This no-action alternative is not favored because the Commission's regulations are more restrictive than FDA and State pharmacy regulations. Moreover, the current regulatory philosophy of linking NRC regulations (e.g., 10 CFR 35.200) to FDA approval of package inserts to ensure the radiation safety of radioactive drugs does not allow NRC licensees sufficient flexibility to use or prepare radioactive drugs. The Commission believes that greater flexibility can be provided while continuing adequate protection of public health and safety.

3. Impact on the Public and the Environment

The final amendments will have no significant impact on the public and the environment. The additional research activities allowed by the final

amendments are expected to be small in comparison to the current total activities involving radioactive drugs containing byproduct material. Therefore, the final amendments will not cause a significant increase in the total activity. Furthermore, allowing compounding could reduce radiation exposures to workers. For example, allowing the use of specific additives could decrease the volatility of certain radioactive drugs, thus, reducing the concentration of radionuclides in air. In other cases, exposures may increase if a licensee markedly increases the amount of compounding, however, such a scenario is extremely unlikely and the workers are protected under the provisions contained in 10 CFR Part 20. Therefore, it is expected that there will be no increase in radiation exposure to the public, health care workers, or the environment, beyond the exposures currently resulting from the preparation and administration of radioactive drugs containing byproduct material. Thus, there will be no discernible impact on the public or the environment resulting from the final amendments.

4. List of Agencies and Persons Consulted and Identification of Sources Used

The NRC held public meetings concerning the preparation and use of radioactive drugs containing byproduct material. Appropriate suggestions from the meetings and from public comments have been incorporated in the final amendments. The following table lists the date, location, and the groups represented at each meeting.

Public Meetings Held

Date	Location	Groups Represented
08/07/91	Rosemont, IL	Board of Pharmaceutical Specialties American Board of Science in Nuclear Medicine National Association of Boards of Pharmacy Committee on Radionuclides and Radiopharmaceuticals of the U.S. Council for Energy Awareness American Pharmaceutical Association American Society of Hospital Pharmacists Purdue University-School of Pharmacy and Pharmacal Sciences University of New Mexico-College of Pharmacy University of Pittsburgh-School of Pharmacy

Public Meetings Held (Continued)

Date	Location	Groups Represented
07/15/92 07/16/92	Atlanta, GA	Agreement States: AL, AR, AZ, CA, CO, FL, GA, IL, KS, KY, LA, MD, NC, ND, NE, NH, NV, NY (including NY city), OR, SC, TX, UT, WA.
11/07/91	Reston, VA	Advisory Committee on the Medical Uses of Isotopes
05/08/92	Reston, VA	
10/23/92	Rockville, MD	

5. Finding of No Significant Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the final amendments will not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The final amendments will relax certain requirements and eliminate specific restrictions associated with the medical use of byproduct material. The Commission believes these final amendments will provide greater flexibility in the medical use of byproduct material while continuing to adequately protect public health and safety. It is expected that this final rule will not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases currently resulting from the medical use of byproduct material.

December 12, 1994

AD69-2
PDR 013

Dr. William H. McCartney, President
American College of Nuclear Physicians

Dr. James J. Conway, President
Society of Nuclear Medicine
1200 19th Street, NW
Washington DC 20036-2401

Dear Drs. McCartney and Conway:

In June 1989 the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) submitted a petition for rulemaking requesting that the Commission amend its regulations to fully recognize the role of nuclear pharmacists and physicians.

As a result of your petition, the Commission has considered and approved final amendments to 10 CFR Parts 30, 32, and 35. These amendments have been published in the Federal Register (59 FR 61767; December 2, 1994) and will become effective on January 1, 1995.

A copy of the Federal Register notice is enclosed for your information.

Sincerely,

/S/

Anthony N. Tse, Project Manager
Regulation Development Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

Enclosure:
Federal Register Notice

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