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ACNP

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From: Carol S. Marcus, Ph.D., M.D.
President, ACNP-CA

Subject: Comments on NRC's Strategic Assessment and Rebaselining Project: Materials/Medical Document no. 7

Date: October 18, 1996

The American College of Nuclear Physicians-California Chapter is so deeply concerned about the poor quality of this document that we are asking the Commissioners to personally study our comments. In addition you should know that we only received the document 2 weeks before the first public meeting, which is (purposefully) insufficient time for the regulated community to review the document, compare notes, and prepare a consensus evaluation. It took me 14 hours to review the document and draft comments. Busy physicians and pharmacists who work for a living should not be abused by NRC in this manner. Four months would be more appropriate. We have made this complaint repeatedly to the Commission for at least the past 6 years. Would you please order your staff to stop this?

Thank you for your attention. I take personal responsibility for the contents of this document, and you may call me at (310) 222-2845 for clarification. My fax no. is (310) 533-7159.

CSM:sfd

JACKMEM.CSM

Acknowledged by card 10/31/96 DMS

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COMMENTS ON NRC'S STRATEGIC ASSESSMENT AND REBASELINING PROJECT: CONSIDERATION OF THE MATERIALS/MEDICAL OVERSIGHT DOCUMENT (NO. 7 OF NRC REPORT, 9/16/96)

OCTOBER, 1996

The American College of Nuclear Physicians California Chapter (ACNP-CA) is pleased to offer comments on the Materials/Medical section of NRC's Strategic Assessment and Rebaselining Project, which we will refer to as "SAR-7". ACNP-CA, ACNP National and the Society of Nuclear Medicine (SNM) have been offering comments to NRC on this subject for the past 10 years, and several cubic meters of material have been sent to NRC pertaining to these issues. As it is unreasonable to ask the current Commissioners to read it all, we ask instead that each Commissioner personally read the submission on NRC's Medical Program that ACNP/SNM made to the National Academy of Sciences-Institute of Medicine (NAS-IOM). Each Commissioner should have received a copy. We also ask that each Commissioner read the entire NAS-IOM Report, not just the Executive Summary.

ACNP-CA has not deviated from the original ACNP/SNM position. ACNP/SNM recommended that NRC end all its regulations for medicine and pharmacy, increase the basic nuclear and radiation science qualifications for physician authorized users, remove most of the paperwork, record-keeping, and prescriptive requirements of 10 CFR Part 20, and enforce only the standards themselves. State Boards of Medicine and Pharmacy and other professional medicine and pharmacy entities would oversee medicine and pharmacy practice as they do now for all other areas of medicine and pharmacy. NRC and Agreement State Radiologic Health entities would only enforce the standards of 10 CFR Part 20 and the evaluation of basic nuclear and radiation science qualifications for Authorized User physicians and pharmacists.

This position, presented on behalf of ACNP/SNM by Dr. Carol Marcus, was virtually identical to the concept presented by Dr. Ivan Selin, then Chairman of the Commission. The NAS-IOM promptly dubbed this concept the "Selin-Marcus Plan".

The NAS-IOM, in its report, basically backed a plan that was supported by the Chairman and the regulated community. Due to the diversity of membership on the NAS-IOM Committee, some degree of naivêté concerning the workings of state and federal governments, and a lack of personal experience with the quality of the CRCPD, some recommendations for national and federal "contributions" to state thinking were made that were not particularly outstanding, and fortunately, not necessary.

While the NAS-IOM and most members of the regulated community favor giving all authority to the states, there is a vocal and intellectually valid minority that does not trust states, and wishes federal "safety net" oversight to ensure that Authorized

User physician qualifications are enforced. NRC's ACMUI is of this opinion, but ACMUI fervently believes that NRC is NOT the appropriate Agency for this task. Unfortunately, when one looks at the other choices (EPA, FDA, OSHA), one is overcome with a similar lack of enthusiasm. The Federal Government today is incapable of fulfilling this role, but opportunity exists for a national organization to issue standards that will be respected by States.

The ACNP/SNM recommendations to the NAS-IOM went further than the "Selin-Marcus Plan". Due to a complete lack of faith that NRC, with its present staff, management, lawyers, and Commissioners, could ever handle such a new role smoothly, appropriately, and competently, ACNP/SNM recommended that Congress go further and amend Section 274 of the Atomic Energy Act (AEA) to phase out NRC's entire materials program over a 12-month period, giving all power to the States. States could contract with other states for radiation management services ("compacts") if desired, and federal entities could self-regulate or contract with states for services, as the federal entities wish. There would be a uniform national radiation standard to be upheld by all states. At present, this standard is 10 CFR Part 20.

However, ACNP/SNM felt that as a national radiation standard, 10 CFR Part 20 is of exceedingly poor quality. In addition, the power of EPA in this area has become onerous, and a new source of a national standard is needed. The source recommended by ACNP/SNM is a modern update of the Federal Radiation Council (FRC) as described originally in Section 274 of the AEA. A Presidential Order transferred FRC power to EPA when it was created, and recission of this order is all that is needed to re-establish an FRC. ACNP/SNM believes that it is an inherent conflict of interest to let the "cops" write the rules. We don't allow local police to write criminal statutes, and we have good reason not to trust "regulatory" police to construct regulatory requirements.

A new radiation protection standard crafted by an unconflicted FRC comprised exclusively of leading ionizing radiation professionals in the nation would become the new national standard. It is a pity that the National Council for Radiation Protection and Measurement (NCRP) has deteriorated so badly in recent years, or it could have been considered for FRC status. That is not a sensible option today.

This portion of the ACNP/SNM concept was not supported by the NAS-IOM, in part because it was not included in its initial mandate by NRC, and in part because the Committee put together by the NAS-IOM was not selected for qualifications in broad restructuring of the manner in which ionizing radiation in general should be regulated in the Unites States today. ACNP/SNM has gone further. It has also produced draft reauthorization language for the materials portion of the AEA that embodies all these concepts. The NRC staff will not need to spend "5 to 7 years" doing this, as stated in SAR-7. Our document was completed

in May, 1995. (This partial reauthorization language was crafted largely by a lawyer who is also a nuclear engineer and a radiopharmaceutical expert, and only took a few weeks.)

It is pathetic, but predictable, that SAR-7, after a year of preparation, fails to explain the legitimate concerns of the professional regulated community, fails to accurately and completely incorporate NAS-IOM and ACMUI recommendations, and fails to describe the dangers to patients perpetrated by NRC (and eloquently described by Dr. E. Gail de Planque when, as an NRC Commissioner, she addressed the NAS-IOM Committee). SAR-7 also fails to describe the parallel "hostile takeover" of Agreement States medical and pharmacy programs that is undermining this entire SAR exercise, rendering this discussion virtually moot. Do the Commissioners understand that the NRC staff and management have prepared an Agreement State "Adequacy and Compatibility" document that requires that essentially all the unrespectable characteristics of NRC's present medical program be required of Agreement States? Do the Commissioners understand that the NRC staff and management, in a last-ditch lurch for power, have announced that NRC will regulate nuclear pharmacies as "manufacturers", instead of as professionals, and that all Agreement States are required to snub their Boards of Pharmacy and accept NRC's regulation (see attachment). Do the Commissioners understand that the licensing guidance for the Radiopharmacy Rule, published Dec., 1994, has not been published and is nearly two years late? Do the Commissioners know that an appropriate guidance document was completed over a year ago, but is being squashed as part of an apparent collusion with FDA? Do the Commissioners know that NRC management has informed at least some Agreement State Program Directors that NRC plans to unilaterally abrogate their contracts with Agreement States and "renegotiate" them? The Commissioners would do a service to the nation to immediately halt the rape of Agreement States, and also remove nuclear pharmacy from "manufacturing", which it most definitely is not, and think of it as a parallel profession to medicine, which it is.

SAR-7 was prepared by individuals with no competence in medicine or pharmacy, who are never going to recommend that their jobs and power be ended. It was a conflict of interest to permit their participation and this document should be ignored.

We will discuss specifically some of the most obvious shortcomings of SAR-7, but our opinion remains unchanged. We recommend the "Selin-Marcus Plan" now, and the removal of NRC's statutory authority for the entire materials program as soon as possible thereafter.

SPECIFIC COMMENTS: SAR-7

1) In the first paragraph of the "Introduction" there is the assumption that present NRC staff and management, all of whom have no competence in medicine or pharmacy, should in essence analyze whether their positions inappropriately regulating medicine and pharmacy practice should be ended in accordance with the recommendations of ACNP/SNM, NAS-IOM, ACMUI, AMA, and APhA. This is flawed Commission judgment. A huge conflict of interest is present. This activity should not have been undertaken by these people, and User Fees were misused for this purpose.

2) In paragraph 2, "operational issues" are to be resolved by the staff, without Commission participation. Given past and present performance of the staff, the Commission needs very much to be involved. "The devil is in the details.", and this staff cannot be trusted or respected for its performance.

3) In "I. Summary: A. Direction-Setting Issue", NRC staff attempts to mislead Commissioners into thinking that the "high levels" of shortlived, gamma-emitting radionuclides used in nuclear medicine in the "manufacture of radiopharmaceuticals" is hazardous. In the first place, "high activities" are not relevant; it is the actual hazards that need to be identified. Most important, the Commissioners may think that "manufacturers" means Mallinckrodt Medical or DuPont-Merck. It doesn't. "Manufacturers" includes centralized nuclear pharmacies under NRC's "new" definition. This leads to a logical impossibility. Millions of doses of radiopharmaceuticals prepared by technologists under physician supervision is not hazardous, but millions of doses of identical radiopharmaceuticals prepared by nuclear pharmacists <u>is</u> hazardous? We are unaware of any radionuclides used by <u>legitimate</u> "manufacturers", professional nuclear pharmacies, or medical practices in diagnosis or therapy that are hazardous at all when authorized users are qualified to handle them. NRC staff assumption of hazard is false and misleading.

4) In "B. Options", the most notable option for its absence is the "Selin-Marcus Plan". Such omission must be assumed to be purposeful.

   Option (1) is an abomination. NAS-IOM, ACMUI, and the regulated community find it unacceptable. NRC, which has failed completely to appropriately regulate byproduct material, cannot be expected to make anything but a similar abortion of the rest. This is not a realistic option.

   Option (2) suggests that NRC can improve. As the staff, management, and lawyers that have caused the present

dysfunctional program are all still in charge, we feel that this option is logically impossible and completely unrealistic.

Option (3) shows how little NRC understands medicine and pharmacy. Diagnostic and therapeutic nuclear medicine are low-risk. Nuclear pharmacy is also low-risk, but sleazed into "manufacturing", it is now high risk! This option defies credibility. It has no scientific, medical, or pharmaceutical justification. The staff evidently believes that as this (and every other) Commission has no personal competence or knowledge in medicine or pharmacy, that it can be cuckolded by the staff. We hope this is not the case.

Option (4) is not quite what NAS-IOM stated, because NRC has quietly moved professional nuclear pharmacy from the NAS-IOM category of "medical" to this "new" definition of "manufacturers". The claim that legislation would be needed to amend Section 81 of the AEA and to name a new lead federal agency does not appear to be credible. Section 104, (appended), the only section of the AEA to mention "medicine" specifically, charges NRC to make "minimal regulation" in this area. NRC's present program is most probably illegal. Limiting regulation to Authorized User qualifications and the standards by 10 CFR Part 20 would seem to be in keeping with the intent of Section 104 of the Act. As far as another federal entity making non-binding "recommendations" to the States, it does not need to be mentioned in the AEA. It was already given to DHHS in the Consumer-Patient Radiation Health and Safety Act of 1981, but few people know about it, especially NRC people. Donna Shalala probably doesn't know about it, either.

Option (5) gets closer to the ACNP/SNM recommendation, with the FRC to make the national radiation standard. There is no evidence to suggest that States will not protect their citizens. In all probability, however, if left to their own judgment, they will not devise a regulatory program that maximized bureaucracy, dysfunctional viciousness, and cost, as NRC has done. It will be small, benign, and cheap, and it will probably be more effective, such is the case in California today, which is far superior to NRC.

5) In "II. Description of Issues", NRC discusses Section 81 of the AEA and conveniently omits Section 104. We strongly recommend that each Commissioner personally read Section 104, the part of the AEA that deals with medicine. At the time the AEA was written, the compounding of radioactive drugs was performed in nuclear medicine departments, and nuclear pharmacy was therefore part of nuclear medicine. Later, nuclear pharmacy became the first acknowledged, board-certifiable subspecialty of pharmacy, and centralized nuclear pharmacies (radioactive "drug stores" which dispense only to physicians, not to patients) became popular. NRC's "medical program" included "pharmacy" from the start. The

effort of NRC staff to carve out pharmacy from medicine and regulate it as manufacturing has been a devious plan of certain staff and lawyers at NRC since 1988. It must be crushed, and the people doing it must be unbudgeted.

6) In "3. Exempt Distribution licenses", one would think that such a category legitimately exists. However, for the medical program, a move to make 1 μCi capsules of C-14-urea "exempt" has been undermined by NRC staff and lawyers, who have recently issued a predecisional document (attached) to deny "exempt" status because it is too difficult to issue NRC and Agreement State exemptions. This is nonsense. In addition, the company petitioning, Tri-Med, is in Virginia, which is an NRC state (see attachment). Instead, they wish to use a general licensing mechanism. NRC intends to publish this as a final rule without public comment. Considering the fact that the NRC Committee to do this includes persons who cannot be trusted in anything medical, we request that the Commissioners intercede and direct the staff to exempt the product. This is a setup for more regulation, none of which will be well received by the medical community. Those who remember the deceitfulness of NRC staff in the "Immediately Effective Interim Final Rule" will understand our reservations, because two of the people who caused that fraud are on this Committee for C-14-urea capsules.

7) In "B. External Factors: 1. Technological Advances", there is discussion pertaining to changes which might be needed in the qualifications of NRC's technical staff. We did not realize that any qualifications existed in the first place. Nuclear medicine and radiation oncology technologists who have lost previous jobs, failed scientists, and leftover nuclear engineers is all we seem to get. None are at all qualified in medicine or pharmacy. None even understand the basic nuclear and radiation sciences that apply to our professional fields. All NRC scientific work is contracted out, usually to "beltway bandits" or underfunded DOE personnel whose conclusions conveniently fit NRC staff desires. All medical decisions are contracted out to medical "consultants", and at least some of these reports are "spin-doctored" by staff to give naive Commissioners the concepts NRC staff wants conveyed. We see no point in having NRC medical licensees pay User Fees to support staff that cannot do their jobs. These licensees also pay for the contractors and consultants as well as the NRC staff and management. It is unfair to pay twice, and obtain such an unrespectable result.

8) In "2. Ageing Equipment", the staff appears to be cultivating a new non-issue upon which to construct make-work to justify useless jobs. The issue of ageing equipment has always been with us. Nuclear medicine began in 1936 and we have handled these issues well without NRC's "help", and so have other medical specialties. FDA Center for Devices and various professional medical oversight groups have a

good handle on this issue. We need NO NRC interference.

9) In "3. External Interest", gross misrepresentation of the staff is evident. First of all, NRC's definition of "misadministration" is medically nonsensical. Is the Commission aware that NRC has ordered the President of ACNP-CA to cease writing "illegal prescriptions" with acceptable administered activity ranges? (The President has not complied, because NRC has no statutory authority over prescriptions.).

As far as "radiation medicine misadministrations that have resulted in deaths", well, this is pretty tiresome. Back in 1976 there were some deaths in radiation oncology due to lack of qualified medical physicists making calculations. This was a failure of NRC in the area of qualifications. Anyway, nothing quite like it has occurred since, although there are isolated problems caused by the same root cause, NRC incompetence in the area of qualifications. There was that one possible nuclear medicine death in the 1960's because a patient got 1000 times the intended dose of Au-198-colloid. The problem was technologist competence. NRC still does not require technologist certification, although some states, like California, do. There was that terminally ill cancer patient about 30 years ago who got intraperitoneal sodium phosphate-P32 instead of chromic phosphate-P32, but it was probably loculated and was never shown to have harmed the patient who was dying anyway. That's about it in nuclear medicine, except for a few burned out thyroids. These rare events have been due mainly to unqualified physicians, unqualified technologists, and human error. In a few cases, they were due to patient dishonesty (e.g. the Tripler affair).

The more recent Indiana, PA incident in which an 82-year old woman with terminal rectal carcinoma died a few months earlier in her nursing home because a high dose brachytherapy source broke off in her and no one realized it, was an example of hysterical NRC behavior, a cover-up of NRC incompetence in mislicensing the product, and the spread of disinformation to inflame the press and public. The Cleveland Plain Dealer, which published terribly misleading stories, was wholeheartedly aided in its yellow journalism by NRC staff. Senator John Glenn, an "antinuke" who can always be counted on to use the nuclear issue for votes, had a Congressional hearing that was contemptible in its entirety. It was hard to tell who won the bullshitting contest, Senator Glenn and his staff or Chairman Selin and his, but the only truth that day came from FDA and CRCPD.

NRC miscalculated the radiation doses to 94 members of the public accidentally exposed to the source (miscalculated upwards by a factor of 2-3 in the best cases and much higher in others), then sent horrifying letters to those 94 people calculating their chances of dying from a cancer caused by

the dose (the calculations were erroneous and not based on scientifically valid data). After succeeding in getting a class action lawsuit started, NRC committed perjury in court. Fortunately, the judge didn't buy any of it and gave summary judgment. The NRC person responsible for the flawed dosimetry was promoted. The NRC individual responsible for the flawed license was put on the IIT to investigate himself and, big surprise, blamed the doctor instead. There is much more to this story, and all of it makes NRC look very bad. There is no way to "fix" a problem like this, except by removing this whole activity from NRC, which has no ability to deal with it intelligently or truthfully.

10) In "4. Full Cost Recovery", the NRC doesn't even consider downsizing as its licensee population decreases. The absence of this option is ludicrous. As none of NRC's staff is competent in this area, downsizing wouldn't do any harm. When the last nuclear reactor is left, do you think it will pay NRC $330 million a year? We doubt it.

The NRC also suggests that changes in Agreement State funding for training and technical assistance may decrease a state's interest in becoming an Agreement State. As NRC has nothing of value to teach in the medical and pharmacy areas, and has no ability to provide technical assistance, either, who wants it? The problem now is that it is difficult to attract good people to work in State Programs, because dealing with NRC bureaucrats is getting more and more ugly. NRC's recent announcement that all State Programs will have to look like "little NRC's", and that State Agreements will be "renegotiated" to force them to look like "little NRC's", must be stopped by the Commissioners. The NRC staff is trying to stop states from becoming Agreement States, rationalize the "taking back" of Agreement States Programs, and trying to get Governors so disgusted with NRC's requirements that they will give NRC back their Programs. It doesn't matter what the NRC Commissioners <u>say</u> about Agreement States; it only matters what they <u>do</u>. And, if the NRC Commissioners stand by hearing, seeing, and speaking no evil while the staff goes merrily along engaged in "State rape", then the Commissioners will be held responsible for management failure.

This a jobs issue. The NRC staff knows that the Materials Program is basically economically nonviable, and that no matter what NRC does, the materials staff will lose their jobs because of the Agreement States Program mandated in 1959 and the cost recovery mandate of 1990. It is a pity that Congress did not explain how a bloated bureaucracy should die out quietly, but it didn't. We now see the staff's last gasp at viability. Surely the Commissioners are not so new or naive that they do not understand this. If they are, they had better stop "cocooning" and get out and visit medical and pharmacy licensees, talk to them, and come to their meetings.

11) In "C. Internal Factor", the Subject of "Business Process Reengineering" is introduced. None of the regulated community has been allowed to participate at all, and we have nothing concrete to evaluate. From all we hear, it seems to be "death by licensing". If it isn't, why aren't we a part of it? And why is it taking so long? If you licensed medical and pharmacy establishments correctly, it would be simple. So, we fear the worst, knowing from experience that our worst fears over the past decade are never as bad as what actually occurs.

12) In "III Discussions", Section 104 is again conveniently not discussed.

As far as discussion of who the "public" is, it should not include patients. It should not even include family members and those who share households with patients. NRC's interference in medical practice needs to end, and by defining "public" as "non-patient" and "non-patient-associated" public, we could make vast improvements in downsizing NRC's program.

The sentence, "The focus should be on the safety significant issues and on providing timely and consistent guidance and licensing that will allow licensees to meet the regulations and standards in the most efficient and economic way", is precious. Medical and pharmacy licensees are not "safety-significant". NRC's "guidance" has been late, medically, pharmaceutically, and scientifically unrespectable, and terribly costly. We have estimated, beginning with NRC's own numbers, that the cost of inappropriate regulation of Nuclear Medicine by NRC results in an expense of about $1 billion/year. As we have about 10 million procedures per year, that is $100 per procedure. We do not need naive NRC dilettantes telling us how to comply with NRC standards. We're smarter than they are, this is our business, and we'll figure it out ourselves, thank you. We do not need to pay User Fees to useless NRC staff to provide us with useless information. And, we do not appreciate having this rubbish foisted upon superior Agreement States because NRC can't stand to be compared with superior "competition".

13) In the section dealing with the role of NRC in regulating the medical use of nuclear material, NRC, in the first paragraph, again uses activity units to infer hazard, rather than making any case for hazard itself. This is misleading.

The second paragraph, which is basically NRC's 1979 Policy, was torn to shreds by the ACMUI. We refer you to the ACMUI analyses during Chairman Selin's hearings.

In the third paragraph, where NRC staff intones that "the Commission has made a concerted effort to improve and strengthen the Medical Use Program.", this is untrue. As the

slow death of the American reactor industry became apparent, the Commission looked for some other reason to justify its existence. It has wreaked havoc with the Medical Use Program, making monstrous mistakes that have no doubt cost many patients their lives. A discussion of harm done by NRC is in the NAS-IOM material submitted by ACNP/SNM.

In the fourth paragraph, the staff states that the degree of regulation of NARM and radiation-producing machines among the States is variable. They infer that some patients are safer than others. There are no data supporting this inference. One can similarly deduce that the State with the least regulation is the smartest, because they don't waste money on needless regulation.

Remember, the NAS-IOM found that NRC's extensive regulations and license conditions protected no one, and were possibly dangerous to patients.

In the fifth paragraph, the staff talks about why the 1992 Medical Management Plan went off track. The true reason is that Ivan Selin began to understand that massive change had to occur, and the staff stalled as much as possible. Once Selin and de Planque were gone, they could ply their tired lies on the next group of naive Commissioners, perhaps with better luck.

In the sixth paragraph, NRC staff markedly overemphasizes the NAS-IOM suggested advisory role of DHHS. NAS-IOM put more faith in States and CRCPD. Does the NRC staff believe that by insisting on passing the program on to another federal agency, that they will just go over to the new agency and continue their jobs?

In the seventh paragraph, the NRC staff talks about a long comment period and several meetings concerning the NAS-IOM report. This delay and unnecessary commenting was unconscionable. Had the Commissioners shown any leadership ability, they would have taken the issue out of the hands of involved NRC staff and worked with the ACMUI and the regulated community to create a practical plan. One does not have a comment period for an NAS report. NRC licensees paid an extra $1.25 million in their User Fees to support this NAS-IOM Report. It should be implemented.

When NRC talks about a "state's" response, it means the response of the State Radiation Control Program Director, not the licensees of the State. In general, these state regulators are as non-expert in medicine and pharmacy as the NRC. Of all the letters from States, the only good ones are from New York, California, and Washington State. The others more or less show state regulators afraid that if NRC goes away, they will have to justify their own programs to their State Legislature, and many could not pass muster, especially against the claims of professional medical and

pharmacy licensees.

NRC asked NRC States if they had the money to regulate their own programs, and the States obediently said "No". They were too incompetent to know that it would not only cost nothing, but that they could make money on it. It's just that they wouldn't have a program that looked like NRC's.

14) In "IV. Options: Option 1", at the end, NRC staff mistakes what the Agreement States said. While most agree that radiation standards for all ionizing radiation should be uniform, this does not necessarily mean that it needs to be under a Federal Agency, and many definitely would not want NRC. This is under a paragraph headed "Reaction of Stakeholders". State Radiation Control Directors are not "stakeholders". The stakeholders are the licensees. ACNP/SNM wrote one letter on behalf of 12,000 people. They wanted no part of NRC and they do not want to be under a different Federal Agency. However, this letter only counts as "one" letter. Needless to say, the response of ACNP-CA was not included in the staff's discussion of "Reaction of Stakeholders", either.

Option 2 is not credible for reasons previously discussed.

Option 3 continues to call manufacturers "high risk", and that includes nuclear pharmacies. As discussed before, this is underhanded NRC scheming and is absolutely untrue.

Option 4, as discussed before, needs to define "manufacturers" to exclude nuclear pharmacies. We have not seen any data to suggest that "real" manufacturers, such as Mallinckrodt Medical or DuPont-Merk are "high risk". Their employees are so much more competent than NRC's, that it is unlikely that any "high risk" problem is occurring. If one exists, it is unlikely that NRC could fix it. The companies would recognize it and fix it themselves.

At the conclusion of this section is a paragraph called "Reaction of Stakeholders", in which NRC staff state that "None of the comments received specifically indicated that there should be no Federal involvement". This is untrue. It is clear from ACNP-CA's letter that we want no Federal involvement. We recommend that each Commissioner personally read the ACNP-CA letters concerning the NAS-IOM Report and concerning the hearings NRC conducted with regard to this Report.

Option 5 does not require that another Federal Agency be named, as discussed earlier. The object is to unbudget the NRC staff from all Federal Civil Service, not just NRC. "Downsizing government" does not mean trading programs. It means ending them.

NRC's argument about different state regulations being a

burden on manufacturers are very self-serving. The fact that this could happen, and in fact occurs now to some extent, is not a justification for NRC's dysfunctional program. It is an opportunity for an FRC to produce standards so sensible, appropriate, and simple, that States will be motivated to improve and move to smoother interstate commerce requirements than they have now.

15) Under "V". Related Issues: A" The NRC staff wonders how it can prevent future violations by licensees. Well, the answer is to throw out most of the regulations and license conditions for medicine and pharmacy and concentrate on the standards of 10 CFR Part 20. How many Part 20 standards violations are there among medical and pharmacy licensees? That is, worker doses greater than 5 mrem EDE per year, organ and anatomic area doses greater than permitted, doses to members of the non-medically involved public greater than 100 mrem/year from a licensee's activities, airborne emissions above legal limits, etc. This is what is important, but NRC gives violations for unimportant and silly things. By and large, physicians and pharmacists, physicists and technologists, radiochemists and physiologists, are all law abiding professionals and are happy to enforce rules that make sense. In all probability, the rules and license conditions that are broken mean that NRC has made bad rules and license conditions. NRC should use its violations as a guide to what it should discard.

In "B", in the area of renewals, NRC should license for the life of the facility, the way the Board of Pharmacy licenses a pharmacy. If the license is very simple and very flexible, the number of NRC employees inventing ridiculous licenses can be decreased to nothing, and a few smart people can take care of new licensees.

In "C", we would point out that by inflicting outrageous User Fees to General Atomics TRIGA fuel fabrication facility in California, the company abandoned the activity in the U.S. and moved it to France. "Regulation by obliteration" isn't very smart.

In "D", the answer is that NRC has an unacceptable materials program. It is not just medicine and pharmacy programs that are intolerable, but academic programs as well. NRC's recent fraudulent coverage of the NIH P-32 incident is a good example of rabid, dysfunctional NRC bureaucrats jeopardizing a perfectly safe activity. For the good of the nation's health research, we need to end NRC's regulation here and in other academic centers. NRC's actions at MIT were similarly unspeakably bad. NIH's radiation professionals and lawyers are making NRC Commissioners look more incompetent each month. The Commissioners need to wake up and take charge.

When the NAS-IOM Report jeopardized NRC jobs, we not only had a panther on our hands, but a wounded panther. NRC staff

is more desperate, more panicked, and more fraudulent than before. This needs to end.

"E", concerning a Federal Agency regulating all radiation safety, is easy to answer. The answer is a loud "No". A set of uniform national radiation standards by the FRC is all we need. These standards cannot be written by any Federal Agency. There isn't one smart enough. NRC spent 17 years screwing up the new 10 CFR Part 20. We do not want it to screw up any more. None of the other Federal Agencies is any better, and EPA, given half a chance, may well be worse.

16) In "V . Commission's Preliminary Views", the Commissioners have been led down the garden path by a staff that controls Commission opinion by selective omission and distortion. The Commissioners need to make a decision based on the NAS-IOM Report, the ACMUI, and the regulated community only. The staff should be ignored, and SAR-7 should be ignored as well.

ACNP-CA would welcome visits by Commissioners and we are sure that ACNP/SNM would arrange visits in states other than California. The Commissioners need to learn the issues, and they will never do so with the staff, the present EDO, or the Office of General Counsel.

ACNP-CA is not sending a representative to any of the three "public meetings" on SAR even though 20% of the nuclear medicine in this country occurs in California. We believe that addressing NRC staff is a waste of our valuable time, and that our message would be spin-doctored, garbled, or just ignored. We are therefore making our case directly to the Commissioners.

ADDENDA

1. Section 104 of the Atomic Energy Act.

2. Agreement State "Adequacy and Compatibility" manifesto to grab the practice of pharmacy and call it "manufacturing". Pharmacy is exclusively intra-state commerce, and has zero "transboundary" implications.

3. Pre-decisional NRC material on Tri-Med C-14-urea petition. Letterhead of Tri-Med, showing it to be in Virginia.

Addendum 1.

SEC. 104. MEDICAL THERAPY AND RESEARCH AND DEVELOPMENT.—

a. 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 purposes 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.

b. As provided for in subsection 102 b. or 102 c., or where specifically authorized by law, the Commission is authorized to issue licenses under this subsection to persons applying therefor for utilization and production facilities for industrial and commercial purposes. In issuing licenses under this subsection, the Commission shall impose the minimum amount of such regulations and terms of license as will permit the Commission to fulfill its obligations under this Act.

c. The Commission is authorized to issue licenses to persons applying therefor for utilization and production facilities useful in the conduct of research and development activities of the types specified in section 31 and which are not facilities of the type specified in subsection 104 b. The Commission is directed to impose only such minimum amount of regulation of the licensee as the Commission finds will permit the Commission to fulfill its obligations under this Act to promote the common defense and security and to protect the health and safety of the public and will permit the conduct of widespread and diverse research and development.

Addendum 2.

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

REGULATION SECTION	SECTION TITLE	CLASSIFICATION ASSIGNED	COMMENTS
§32.1	Purpose and Scope	3.b.	
§32.2	Definitions		
	Dose commitment	See 10 CFR §20.1003	This term and definition are superseded by the new term and definition in 10 CFR Part 20, "committed dose equivalent." Thus, if the 10 CFR Part 20 term and definition are adopted by a State, the adoption of this term and definition are not needed.
	Lot Tolerance Percent Defective	3.a.	
§32.3	Maintenance of records	3.b.	
§32.8	Information collection requirements: OMB approval	3.b.	
§32.11	Introduction of byproduct material in exempt concentrations into products or materials and transfer of ownership or possession: Requirements for license	Paragraphs (a) and (b) are 3.a.; and (c) is 2.	

REGULATION SECTION	SECTION TITLE	CLASSIFICATION ASSIGNED	COMMENTS
§32.71	Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under ~~general license~~	2	
§32.72	Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35	2	Pharmacy: not interstate commerce. intra state. not "manufacturing" — Compounding
§32.74	Manufacture and distribution of sources or devices containing byproduct material for medical use	2	
§32.101	Schedule B-prototype tests for luminous safety devices for use in aircraft	2	
§32.102	Schedule C-prototype tests for calibration or reference sources containing americium-241	2	
§32.103	Schedule D-prototype tests for ice detection devices containing strontium 90	2	

- A number of terms are defined in more than one Part in 10 CFR. For purposes of consistency, the tables show the compatibility determination for the definition in the most appropriate Part and refer to that Part at all other occurrences of the term. See, for example, the definition of "restricted area" in the table for Part 19, Section 19.3.

- Unless otherwise indicated in the tables, the compatibility or health and safety designation applies to the entire section of the Part. See, for example, the table for Part 20, Section 20.2003, where individual paragraphs are assigned different components.

Key to classifications:

1 =	Basic radiation protection standard or other regulation which the State should adopt with (essentially) identical language.
2 =	Regulation/program element with significant transboundary implications which the State should adopt with essentially identical language.
3.a =	Regulation/program element, the essential objectives of which should be adopted by the State, to avoid conflict, duplication or gaps. The manner in which the essential objectives are addressed need not be the same as NRC provided the essential objectives are met.
3.a.S =	Regulation/program element involving specific statutory direction, the essential objectives of which should be adopted by the State in a manner at least as stringent as NRC.
3.b =	Not required for purposes of compatibility; however, if adopted by the State, must be compatible with NRC.
NRC =	Not required for purposes of compatibility; the regulatory area is reserved to NRC. However, a State may adopt these provisions for purposes of clarity and communication, as long as the State does not adopt regulations or program elements which would cause the State to regulate in these areas.
3.b* =	Not required for purposes of compatibility; however, required for purposes of health and safety. The State should adopt the essential

Addendum 3.

NOTE relating to letter from Carol S. Marcus, ACNP, dated October 18, 1996
Subject: Comments on NRC's Strategic Assessment and Rebaselining Project: Materials/Medical Document No. 7

The predecisional material referenced in the Addenda on page 14, item 3, has been removed from this package.

the diagnostic test, but this would add expense, inconvenience, and delay to an otherwise straight-forward procedure.

This alternative serves as the base case from which the other alternatives are evaluated.

Alternative 2 - Grant the petition via an exemption to permit physicians who are not "authorized users" to receive and use capsules containing 1 μCi of ^{14}C-urea

This alternative would permit the receipt and medical use of capsules containing 1 μCi ^{14}C-urea by physicians who are not authorized users.

However, manufacture and distribution of exempt materials can only be made by NRC licensees; Agreement States licensees who intend to manufacture or distribute such capsules would need to obtain an NRC manufacture and distribution license in addition to their Agreement State license (10 CFR 150.15(a)(6)). Therefore, this alternative is not recommended.

Alternative 3 - Grant the petition via a general license to permit physicians who are not "authorized users" to receive and use capsules containing 1 μCi of ^{14}C-urea

This alternative would permit physicians who are not authorized users to receive and use capsules containing 1 μCi ^{14}C-urea for medical use under a general license.[1]

This alternative is preferred over the base case (Alternative 1) for the following reasons:

o Health and Safety

As noted earlier, a detailed safety analysis was performed that analyzed public, worker, and patient radiation safety hazards associated with

[1] The concept of a general license for medical use is not new. Prior to 1967, Part 35 regulations permitted the medical use of certain radioactive drugs under a general license to physicians who were registered. Registration certificates would not be necessary for ^{14}C because, as discussed in the SAFETY ANALYSIS section, radiation safety concerns associated with the use of these capsules are insignificant. The general license was deleted from Part 35 because of the low level of use.

TRI-MED
Specialties Inc.

1500 AVON STREET EXT'D
CHARLOTTESVILLE, VA 22902
PHONE (804) 977-8711 FAX (804) 977-8760

December 5, 1994

Dear Doctor,

Tri-Med Specialties, Inc. has petitioned the NRC to make a rule change enabling the ^{14}C Breath Test to be distributed to physicians without an NRC or agreement state license. I have included a copy of the petition as it was published, and a copy of a correction letter sent to the NRC. This rule change would make the test more economical to perform and more readily available to patients.

This petition was published in the Federal Register on December 2, 1994. It is now open for public comment for the next 75 days. At the end of the comment period, the NRC will take into consideration all comments and make a ruling on our petition.

We would greatly appreciate your help in this matter by sending a letter to the NRC voicing your opinions. I have included a sample form letter. You may use this letter as is or alter it as you please. The deadline date for comments to be received by the NRC is **February 10, 1994**.

Thank-you in advance for your letter.

Sincerely

Barry Marshall

Barry J. Marshall

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