

July 25, 2001

Ronald E. Zelac, Ph.D.
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U.S. Nuclear Regulatory Commission
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Dear Ron:

Thank you for coming to the Society of Nuclear Medicine (SNM) Annual Meeting in Toronto this past June to discuss NRC's planned new medical regulations, 10 CFR Part 35. In our discussion after the session devoted to this topic, you asked that I document to you in writing examples of where license conditions add requirements not in the regulations or remove the rights given in the regulations (i.e. negate the regulations).

In your talk, I objected to your use of the usual misleading NRC phrases to describe the Part 35 requirements, such as "risk informed" (there was no legitimate risk analysis used in a competent manner by NRC), "performance based" (performance standards were ignored in favor of prescriptive regulation), and "unprecedented public participation" (we came and we commented but every single significant point made by the expert Nuclear Medicine community was ignored). Most significant by its absence was the fact that you did not mention NRC's "secret" regulations, the license conditions that constitute *de facto* additional regulations and in some cases even negate the privileges in the Part 35 regulations, two of which were won after Petitions were submitted to NRC by SNM/ACNP or me *at NRC's request*. When you adamantly stated that the Commissioners had insisted that the license conditions impose no requirements not clearly stated in the regulations, I found it incredulous. It is clear to me that the Proposed Part 35 has been a diversionary tactic to cover the real rulemaking, which is in "licensing space" (as Kathy Haney of NRC called it). That is, while NRC was raising unimportant issues for public discussion---straw men, essentially---the real damage was being done behind closed NRC doors, not discussed at public meetings or by NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI), and hidden in several thousand pages of diverse documents in as clandestine a mode as possible. While most (but not all) of these documents became "public" documents, bits and pieces of information were cleverly embedded in different documents so that it was unclear, by simply reading one document, to know what was really going to happen. Certain portions are still confusing and vague.

Regulation by license conditions is not new; unfortunately, it has gone on for over 50 years. For example, in a 1954 memorandum by S.R. Sapirie it is stated that the Federal Register should be the central repository for all federal regulations of the then Atomic

Energy Commission. The memorandum further states that "Section 3(a) of the Administrative Procedures Act provides that: (a) Rules. Every agency shall separately state and currently publish in the Federal Register... (3) substantive rules adopted as authorized by law and statements of general policy or interpretations formulated and adopted by the agency for the guidance of the public, but not rules addressed to and served upon named persons in accordance with law. No person shall in any manner be required to resort to organizations or procedure not so published." (see <http://search.dis.anl.gov/plweb/cgi/mhrexpage.pl?0726743+1-27+ free>, p. 9 of document). In addition, in a Petition for Rulemaking submitted to NRC by SNM and the American College of Nuclear Physicians (ACNP) in 1989 regarding nuclear pharmacy and nuclear medicine, the issue of license conditions negating regulation was a central issue.

The purpose of this letter is to document to you that the staff and management responsible for the Part 35 rulemaking and its associated licensing have ignored the Commissioners' stated policy, and that the "disconnect" between what Commissioners say and what the staff and management do is detrimental to patient care in the United States. I have opposed the entire rulemaking package because I understand it and its ramifications. I present in this letter several examples of staff and management licensing problems, and assume that the Commissioners were unaware of it, or at least largely so. This is not a comprehensive list of problems, but just the selection of a few obvious ones.

Example No. 1: Compounding of Radiopharmaceuticals

While the proposed new Part 35.100, 200, and 300 continue to state that Authorized User Physicians and Authorized Nuclear Pharmacists involved in the practice of Nuclear Medicine and Nuclear Pharmacy can use *any* byproduct material in any radioactive drug, licensing takes away this necessary privilege. The "Radiopharmacy Rule" of Dec. 2, 1994 followed the submission of a Petition by SNM/ACNP, *requested by NRC*, to stop the new Part 35 of 1987 from jeopardizing patients' lives, and even the FDA publicly chastised NRC for passing dangerously limiting regulations and license conditions. By NRC's move now to change requirements for manufacturers, *it will be nearly impossible for us to obtain the raw materials with which to make our drugs (NUREG-1556 vol. 12; see also NUREG-1556 vol. 20 p.E-32 for "Manufacturers and Distributors not authorized to distribute to medical licenses")*. While we can presumably use anything we can get, it will now be extremely difficult to get anything we can use. In addition, the draft medical regulatory guide showed in a sample license that Nuclear Medicine practitioners may use only FDA-approved or accepted therapy drugs for FDA-approved or accepted indications. This is clearly against the old and proposed new 10 CFR 35.300. Written and verbal comments pertaining to the manufacturer's NUREG and the medical NUREGs were given by me and by the California Chapter of ACNP to NRC in 1997 and 1998, but have been ignored.

NRC Inspection Manual TI 2800/029, rev. 1, defines as an important "focus element" of Nuclear Medicine inspections that NRC inspectors should check for "unauthorized uses of licensed material". Also, this document states, "The inspector, through observations

of ongoing activities, interviews of personnel, and review of records, should verify that no unauthorized use of materials occurred.", and discusses violations "for administration to a patient of material that was not authorized for medical use". It is painfully obvious that NRC intends to write licenses that do not reflect the content of 10 CFR Part 35. This is even more surprising in light of the Commission's new Medical Policy Statement (Fed. Reg. 65[150]: 47654, 3Aug.2000), which states in part, "2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public."

I see that you are the senior author of the Manufacturer's NUREG (Vol. 1556 no. 12), and wonder if you were aware of the early history of this document. It is my understanding that you were not working at NRC when the precursor for this NUREG, Draft Regulatory Guide DG-0007, written by Donna-Beth Howe and Sam Jones, was published in March, 1997. On April 29, 1997, I sent comments to Hugh L. Thompson, Jr., then Deputy EDO, because of huge problems I saw with the draft. Hugh directed a telephone meeting to take place consisting of Larry Camper, Donna-Beth Howe, Kathy Haney and me to resolve the problems. This took place on 5/21/97 from 0800 to 0910 hrs. Promises to resolve the problems were made by Larry, and Sam Jones was to write a letter explaining how the problems would be fixed. I wrote another letter to Hugh Thompson after the conference call (dated May 27, 1997), and received a letter from David L. Morrison, Director of the Office of Nuclear Regulatory Research, written May 30, 1997, assuring me that my written comments and those of the conference call would be noted and considered for the final document. Copies of the three letters are appended. No letter ever came from Sam or Larry as promised. If you were not aware of these letters and issues, one wonders why not. As senior author of the final document, perhaps you are being "set up"?

Example No. 2: NRC Will Determine Medical Care for Individual Patients

Due presumably to the fact that NRC will not, by license, permit physicians to prepare, obtain, or use categories of radiopharmaceuticals for all uses judged appropriate by the Authorized User Nuclear Medicine Physician (despite the regulations stating otherwise), NRC has created a fascinating "loophole". Described in NUREG-1556 Vol. 20 beginning p. 4-22, NRC describes a complex mechanism by which medical licensees can claim the need for a "humanitarian or emergency exemption". That is, when a physician is forbidden by his license to use a particular drug for a particular indication, the needs of that particular patient must be justified to non-medical NRC employees, and NRC will decide whether the particular patient may be cared for as the physicians wishes.

It would appear that if the NRC has decided to practice medicine without a license, that such a decision would have been made only with the blessings of the Commissioners, Congress, the ACMUI, and the public, after significant national discussion and input. Such a major decision seems to have appeared only in an internal NRC document informing NRC employees how to write licenses.

Several new therapy radiopharmaceuticals that should soon gain FDA approval are effective in treating patients with uniformly fatal cancers. If NRC intends to limit the clinical indications for which these radiopharmaceuticals may be administered, some patients may die. Others may have severe adverse reactions to other treatments that might not have been necessary if the NRC had not prevented the patient from being treated with the new radiopharmaceutical in the first place. I have not seen the final licensing requirements for Nuclear Medicine (NUREG-1556 Vol. 9 is not yet publicly available); I have only seen the draft NUREG and read these other NRC documents with alarm. I believe that laying bureaucratic obstacles before a physician that *de facto* prevent the use of this patient-specific exemption is fraud, and that this mechanism was designed to be unusable. Who at the NRC is qualified to make medical judgments on individual patients, and take clinical responsibility for outcome? Where is this in the Code of Federal Regulations? If the Commissioners have not authorized this, and it is certainly against the Medical Policy Statement, why is it happening?

Example No. 3: The "500 mrem Patient Discharge Rule" Appears Jeopardized

In December of 1990, when the new Part 20 was unveiled, NRC asked a member of the ACMUI (me) to write a Petition keeping the 500 mrem limit to members of the general public from patients receiving radiopharmaceuticals, using the mechanism provided in 10 CFR 20.1301(c). This was promptly done, and after seven years, the Petition was granted, albeit with excessive bureaucracy and paperwork. In NUREG-1556 Vol. 20, NRC revisits 10 CFR Part 51, stating that those licensees previously exempted from submitting Environmental Assessments (EA) will lose that exemption if their activity is not conducted ALARA. Medical licensees have always been exempted. It is possible that NRC means to include medical licensees in this ALARA trap, but I am not sure. Sending patients out of the hospital when they contain radioactive material can be considered to not be ALARA for members of the general public. In addition, on p. 4-18 it states, "For example, an EA would be required for discrete sources released to the environment, which originated on-site, and which may not be recovered at the conclusion of the study or decommissioning." This certainly describes our patients. In addition, on p. K-2 (c) it states, "The licensee must provide enough information to determine that the requirements in 10 CFR 20.1301(a) will be met. The licensee must also address how it will determine that dose limits to members of the public and other patients in unrestricted areas from multiple therapy patients or subsequent hospital stays in *the same calendar year will not exceed 100 mrem per calendar year.*" (italics are NRC's). Can it be that NRC will not permit the 500 mrem limit, despite the Part 20 and Part 35 regulations, without an Environmental Assessment, perhaps for each of our therapy outpatients beyond a certain administered activity?

Example No. 4: Use of Procedures in NRC NUREGs

The proposed new Part 35 requires licensees to have many procedures in place (none of which in my opinion are appropriately justified), but those procedures do not need to be submitted for review. (That alone seems very strange. If NRC believes a procedure is mandatory, NRC must believe that operating without one could be hazardous. Therefore,

one would assume that NRC would have to approve the procedures ahead of time.) If any mishap occurs, an inspector will review those procedures, erroneously presuming that lack of appropriate procedures, or lack of teaching technologists those procedures, or lack of supervision of the technologist is the reason for every mishap. That is, human error becomes criminalized. The regulations do not detail the precise procedures required, and sample procedures in the NUREGs have always been considered as samples, and not a requirement (formal letters from Robert Bernero and Carl Paperiello of NRC have formally documented this). While you spoke of the freedom licensees have in writing their own procedures, this was most disingenuous. NUREG-1556 Vol. 20 makes it clear that each *acceptable* procedure needs to be substantially equivalent to NRC's. As NRC's procedures are generally medically hopelessly naïve, of poor scientific quality, and/or unnecessarily time-consuming and expensive, licensees will be required to have bad NRC procedures or be faced with a series of trumped up violations for not having "adequate" procedures. As one cannot practice good medicine with NRC's version of the required procedures, a licensee will either be in violation of his procedures in order to practice good medicine, or practice good medicine with good but "incompatible" procedures which then results in violations. This is a classic "Catch 22". Is this what the Commissioners intended the staff to create? A scheme to create fake "safety" violations? Even the Conference of Radiation Control Program Directors (CRCPD) understands this threat to Nuclear Medicine practitioners, and complained about it publicly. Comments against this whole mechanism and against NRC's individual draft procedures were submitted to NRC by the California Chapter of ACNP, even before it was apparent that these procedures will essentially be mandatory, but appear to have been ignored.

The above four examples are only a small selection of examples in which licensing creates new requirements not in the regulations, or reverses a regulation. There are many more, and many of these others stem from a secret document, SP99037, NRC's PG83-2, Rev.1, Supplement 1, which was sent to Agreement State Program Directors in June, 1999. This document was prepared by Donna-Beth Howe. The document was "locked out" for members of the public, who could not access it from NRC's Agreement States website without a password. Agreement State Program Directors were not even allowed to show it to their medical advisory committees for analysis, and NRC did not show it to its ACMUI. A request under FOIA went out from SNM/ACNP, but they were told they could not have it. The accidental disclosure of the document by an Agreement State to a member of its medical advisory committee resulted in the contents becoming known. It seems that most of the unacceptable changes planned in NRC's licensing process stem from this document, which is basically finalized as NUREG-1556 Vol. 20. Significant policy change in NRC's licensing procedures should be an open and public issue, not a secret one. It would appear to be a decision of the Commissioners, as Commissioners make policy. Was it? In any case, nothing in the regulations states that the entire concept of licensing has been revised to become a system of parallel, but clandestine, *de facto* rulemaking.

I do not know who wrote the NRC Inspection Manual TI 2800/029, rev. 1, as there is no name on it. However, one can infer licensing patterns from its content, which is onerous.

Unraveling these licensing issues is liable to be difficult. If I can help you, just contact me.

Thank you for your attention and consideration, and your obvious desire to do the right thing.

Sincerely,

A handwritten signature in cursive script that reads "Carol".

Carol S. Marcus, Ph.D., M.D.

Investigator, Harbor-UCLA Research and Education Institute

And

Prof. of Radiological Sciences and of Radiation Oncology, UCLA