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The Honorable Shirley Ann Jackson
Chairman, USNRC
Washington, DC 20555

Dear Chairman Jackson:

Having read NRC's and Isotopics' coverage of the Ball Memorial Hospital affair, I am concerned with NRC's allegations. While all the facts are not available to us, those that are make certain NRC statements appear to be conflicting or erroneous.

In the first place, there are commonly times when it is entirely medical necessary and appropriate to increase administered activity for diagnostic nuclear medicine procedures "to minimize patient discomfort, reduce imaging time for critically ill patients, and to enhance the clarity of images for studies performed on obese patients". There are other situations in which it is appropriate, such as a prolonged interval between administration and imaging because of various factors, one of which is the interposition of dialysis. Indeed, it may constitute malpractice not to raise the administered activity, as critical diagnostic information may be missed if image quality is poor.

NRC appears to be outraged that technologists made these decisions without first obtaining permission from an authorized user physician. NRC should know that in a large number of practices, technologists decide on the administered activity in the first place, based on the fact that the physician may be poorly competent in nuclear medicine and willingly gives this responsibility to technologists. Technologists who are unsure as to appropriately administered activity typically ask nuclear pharmacists, or call other licensees and ask them. NRC's qualifications for authorized user physicians manage to include many poorly competent physicians. In addition, the physician, even a highly qualified one, may not be in the department at the time of radiopharmaceutical administration and these decisions must therefore be made by technologists. Many physicians come in at 5 PM to read out procedures performed by technologists who worked independently all day. NRC cannot act surprised that this goes on; NRC has fostered such practices, and is well aware of them. Much depends on the understanding between the authorized user physicians and the various technologists. This is not for the NRC to judge, but for the physician and Board of Medicine to judge. Has the NRC consulted the physicians and the Indiana medical board?

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NRC does not appear to understand that decisions related to administered activity of diagnostic radiopharmaceuticals of the sort mentioned in this case are trivial and well within the competence of certified nuclear medicine technologists. Despite NRC's proclamation to the contrary, there is no a priori problem with this practice. Done correctly, it enhances medical quality and patient care.

To illustrate the above points please consider the following two related examples. (1) X-ray technologists decide on their machine settings and take retakes as necessary. They do not bother radiologists with these details. (2) A physician may order one or two tablets of an analgesic to be given every four to six hours in the event of pain, and a nurse decides whether to give one pill or two, and at what time interval, and what constitutes "pain". After 12 hours, an analgesic dose can vary by 300%, with no further physician involvement.

NRC appears to be judging medical practice, which is outside NRC's authority and competence. NRC, or more likely a qualified medical consultant, determined "that there were no health injuries to the patients". The harmlessness of these doses is, of course, obvious. The average diagnostic nuclear medicine procedure imparts a radiation absorbed dose in between yearly background radiation levels at sea level and in Denver, Colorado. For NRC to infer that there is even the legitimate possibility of harm means that NRC's staff and management are being purposely untruthful. They are probably trying to generate radiophobic hysteria to justify their jobs. Part of NRC leadership's responsibility is to see to it that such desperate and destructive behavior is halted. On the other hand, I am sure that there were significant health benefits to the patients, in that the quality of diagnostic procedures was improved. It would appear that NRC has missed the point entirely. Why did NRC avoid consideration of benefits?

In addition, it would seem that even if an authorized user physician had approved an increase in administered activity, that increase would, in some cases, have been above the limits in their NRC license, which would have meant that it would have been a license violation to administer the increased activity anyway. The alterative to purposeful medical malpractice to satisfy NRC (!) would then be to administer the higher activity to achieve good medical practice but fib about the dose. Why in the world has NRC issued a license telling a physician what doses he/she is allowed to prescribe? Did NRC make a procedure manual into a license condition? If so, this is purposeful malevolence by NRC,

as a medical procedure manual is merely a general starting point for procedure description, and was never meant to limit the conduct of the healthcare professionals who must be free to tailor any procedure to individual patient needs. NRC has no business limiting a physician to a procedure manual when infinite variability is required. It is neither possible nor sensible to try to write a procedure manual for infinite variability. This point was settled, I thought, when Admiral Carr was Chairman. The point is obvious. Why does your staff think that it can start its dysfunctional mischief all over again and get away with it? I request that you immediately nullify any license conditions for any and all medical licensees that limit physician judgment. Your job is not to harm patients. Your job is to insure that authorized user physicians understand how to use byproduct material safely. It is the authorized user physician who then decides how to use byproduct material in his medical practice, not NRC. And, if the physician authorizes technologists to vary diagnostic doses, that is the physician's option.

NRC has also intimated that billing for a diagnostic procedure in which higher administered activities were used is fraudulent. That is blatantly untrue. The procedure does not define administered activity as a requirement. Health care professionals are expected to use judgment and administer whatever is necessary. If anything, Ball Memorial may have underbilled the cost of the drug because they actually used more than they billed for, but the difference is probably quite small.

While it is theoretically possible that Ball Memorial could have petitioned for a license amendment, we all know the reality of attempting that farce. After a great deal of licensee time and expense, nothing will happen but NRC stalling and ultimate refusal. The purpose of such license conditions is to abuse medical licensees. These requirements have nothing to do with legitimate public health and safety concerns, are not part of the Code of Federal Regulations, and have been arbitrarily required by NRC staff without the benefit of public process under the Administrative Procedures Act, ACMUI review, or oversight by any competent group, none of which exist at NRC in medical anything.

The last point I would like to make concerns lying. NRC staff lies to licensees, NRC management, NRC Commissioners, Agreement States, the media, the Congress, and each other. Lying and extreme spin-doctoring are an essential part of the intrinsic culture of NRC's "Medical" Program. If NRC employees are rewarded for lying, as they are, why does NRC leadership get so self-righteous when a licensee lies harmlessly in order to take care

of a patient and save his own skin as well? While I don't condone lying, NRC puts licensees into an otherwise impossible situation. Harmless lies are the least harmful way of fulfilling one's medical obligations and avoiding the wrath of a dishonest federal agency. If lying is a problem to NRC, it should first clean up its own dishonesty. That will make licensee lying all but disappear.

So what, then, is this case at Ball Memorial really about? That NRC wrote a stupid license, and that the technologists had to cheat to get the job done correctly? There is nothing suggesting overdoses to patients, but the benefits to the patients in terms of better procedures is not even mentioned. In addition the safety benefits to patients are not mentioned. After all, minimizing time that critically ill patients spend in Nuclear Medicine is important. A patient breathing fast can only do so for a short time before he needs to be intubated. Once he is intubated one cannot perform a ventilation lung scan with commonly available radiopharmaceuticals, such as Xe-133. It is safer to increase the administered activity, get the scan, and have the patient intubated if necessary, than risk respiratory arrest with a slower procedure or risk no study at all. No procedure could cause diagnostic problems and lead to pulmonary angiography, which is invasive and somewhat dangerous; in certain patients it is so dangerous that a radiologist will not even attempt it. The patient may then be treated with a dangerous drug without needing it, or not get treated with the drug and die of a pulmonary embolism.

Does NRC enjoy interfering with patient care and being a danger to patients? Does NRC think it's fun to prevent a physician or other health care professional from doing the best job he can for his patient? Does NRC wish to have a medical malpractice suit filed against it for preventing a physician from doing his best to care for his patient, and thereby causing avoidable morbidity or mortality? Perhaps NRC needs to reread the NAS-IOM report of 14 Dec. '95.

It appears that certain NRC staff and management who fear for their positions and power have concocted nonsense and succeeded in fooling NRC leadership completely. If anything terribly inappropriate occurred at Ball Memorial Hospital, and the only thing inappropriate so far appears to be the behavior of NRC licensing staff and management, many of the nation's knowledgeable professionals are trying to figure out what it is.

While you seem to have terrified Ball Memorial Hospital, you have failed to make any valid points to the knowledgeable professional public.

Thank you for your attention and consideration.

Sincerely,

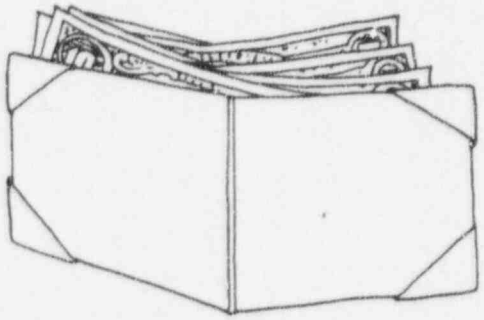
Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
Harbor-UCLA Medical Center
and
Professor of Radiological Sciences,
UCLA
and
President, American College of Nuclear
Physicians, California Chapter
and
Expert Medical Reviewer, Medical Board
of California

enclosure

cc: Commissioner Greta Dicus
Hugh Thompson, Deputy EDO
Commissioner Kenneth Rodgers

OIG Fines Ball Memorial $300,000

On April 19, 1996, the U.S. Attorney for the Southern District of Indiana announced a settle of potential civil litigation against NRC-licensee Ball Memorial Hospital (Muncie, IN) and federal charges against two former hospital employees. The civil settlement has resulted in the payment of $300,000 by the hospital to the U.S. government. The U.S. Attorney has files charges against two former employees with violating various provisions of the Atomic Energy Act. These individuals can face a term of imprisonment of up to 2 years and a fine of up to $250,000.



In 1993, the NRC began an investigation of the hospital because of alleged violations of NRC regulations. NRC's investigation revealed that nuclear medicine technologists at the hospital failed to obtain approval from authorized physicians prior to increasing radiopharmaceutical dosages of certain patients to reduce imaging time. The investigation also found that dosages exceeded the allowed ranges in Ball Memorial's NRC license by as much as 40 percent and that the technologists falsified recorded dosage levels. The dosages were increased for imaging studies of the lung, liver, bone, and gastrointestinal tract using Tc-99m and Xe-133. NRC inspectors did not identify medical misadministrations, as defined in 10CFR35.2, as a result of this practice of administering high doses for diagnostic imaging. According to the licensee, one technologist told licensee officials that dosages were increased to minimize patient discomfort, to reduce imagine for critically ill patients, and to enhance the clarity of images for studies performed on obese patients.

The licensee conducted an internal investigation. Based on those findings, the licensee initially suspended two nuclear medicine technologists from all NRC-licensed activities. Subsequently, the [illegible]e terminated the employment of one of the two individuals; the other individual was allowed to continue to perform non-NRC-licensed activities. Some of the licensee's other corrective actions included assigning a pharmacist or a radiologist to verify all radioisotope dosages, implementing a unit dose system, obtaining the services of an assistant RSO, and conducting monthly and quarterly audits of the Nuclear Medicine Section for a least one year.

A separate investigation by the Office of the Inspector General (OIG) of the Department of Health and Human Services found that the hospital submitted claims to a Medicare intermediary for tests of certain patients who received allegedly higher dosages. The facility has taken corrective action requested by the NRC. The increased level of dosages did not cause any health injuries to the patients.

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