# Released Nuclear Medicine Patients, Security Checkpoints, and the NRC

**TO THE *JNM* NEWSLINE EDITOR:** We read with interest the Newsline article by Katz and Ansari (*1*) that appeared in the December 2007 issue of *The Journal of Nuclear Medicine* (*JNM*) concerning nuclear medicine patients potentially triggering radiation detectors. According to this article, many patients, particularly those receiving radiopharmaceuticals in diagnostic-only facilities, are unaware that they emit detectable levels of radiation and thus may trigger radiation alarms, because many of the surveyed health care professionals: (a) do not so inform these patients; and (b) lack adequate training in patient communication. However, we believe that the study was poorly designed. Not only do the data collected require further analysis and evaluation, but new data would have to be collected because the relevant nuclear medicine professionals were not adequately surveyed.

Based on interviews with professionals involved in nuclear medicine procedures, the study attempted to discover if patients receiving radioactive materials for diagnosis and treatment are informed of the radiation alarm issue, i.e., that they are radioactive and could trigger radiation monitoring alarms. The data, as collected by Nuclear Regulatory Commission (NRC) inspectors, suggest that those professionals interviewed were familiar with patient release procedures. Most respondents indicated that patients are informed that they may emit detectable levels of radiation (100% after therapy, 80% after diagnostic administrations). However, many patients are not informed that their radioactivity level may activate radiation alarms (80% after therapy, approximately 55% after diagnostic administrations). Although no specific regulations require licensees to provide such information, SNM and the American College of Nuclear Physicians (ACNP) have recommended informing patients and providing them with documentation of radiopharmaceutical administration (*2*). In our post-9/11 world, radiation detectors are appearing in many public places, and, therefore, patient education and awareness are necessary.

Eighty-nine professionals were interviewed in the study reported by Katz and Ansari: 11 radiation safety officers (RSOs), 9 authorized users (AUs), 12 physicists, 43 nuclear medicine technologists, and 14 managerial staff. No breakdown was given for these AUs (i.e., board certification in nuclear medicine, diagnostic radiology, cardiology, endocrinology, or radiation therapy). Only 9 of 89 (10%) individuals interviewed were physicians. This is odd, because patient communication should be the domain of the AU and not any others, unless they are so designated by the AU because of sufficient training and knowledge. It would certainly be a good idea for the AU to educate his or her staff about the radiation alarm issue. According to a 2003 NRC Information Notice (*3*), it is the AU who has the responsibility to evaluate the patient's capability to follow any release instructions required. The purpose of this Information Notice was to alert licensees of an event in which a radiation detector was set off by an appropriately released nuclear medicine patient who had been provided with but failed to follow written instructions (which included not using public transportation for 2 days). Of interest is the NRC statement in this document: "NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so" (*4*).

About 50% of those interviewed in the Katz and Ansari article stated they had no formal training in patient education or patient counseling. The authors of this study concluded that training in effective patient communication, particularly for professionals in those facilities offering only diagnostic procedures where less patient communication was found, would therefore be beneficial. Again, these individuals were not identified, but one must assume they were mainly RSOs, physicists, and managerial staff, as well as technologists. These individuals should have no official patient release communication responsibilities at all, unless they are appropriately so designated or the RSO is also a physician.

We agree that all released nuclear medicine patients (therapeutic as well as diagnostic) should be informed of the possibility that they may trigger radiation monitoring alarms and should be given documentation to provide to appropriate personnel should this occur, and this is SNM's position. Although many, if not most, board-certified nuclear medicine AUs may already be doing this, it may be that AUs performing diagnostic-only procedures are cardiologists and diagnostic radiologists, who may not be SNM members and therefore are less likely to inform patients or educate their staffs about the possibility of setting off radiation detectors. The NRC inspectors had access to all "relevant" health care professionals within each studied facility but apparently chose not to focus their interviews on the relevant AUs.

Although the NRC has no requirement for licensees to educate patients about the radiation alarm issue, the AU "offenders" should have been more specifically identified in

order to assess who may benefit most from an outreach program reiterating the information contained in the 2003 NRC Information Notice, as suggested in the Newsline article. It is important to note that the Information Notice states that NO ACTION is required by licensees and, instead, simply requests that licensees consider 2 voluntary actions: (a) provide all released patients with an appropriate explanation about the potential of alarming radiation monitoring equipment; and (2) consider providing all patients with the licensee's business card and written information for law enforcement use, stating that the patient poses no danger to the public and that their travel/movement in public is allowed by NRC medical use regulations. The article gave the illusion that the readership of *JNM* was broadly and largely at fault and, in fact, might have been more appropriately targeted to a nuclear cardiology and/or diagnostic radiology audience. Although it is not a prerequisite for AUs to be members of SNM or even read *JNM*, it is likely that they will be better informed of current issues of concern and best approaches for dealing with these issues through SNM informational resources than through NRC Information Notices, as the article does appear to indicate. The data would have to be reanalyzed and new data would have to be collected to determine if this were actually the case.

The ALARA issue raised in the article has limited relevance, because most of the uninformed patients identified in the study received diagnostic administrations requiring no release instruction at all. These patients should go about their daily lives as usual and not be burdened with any unnecessary restriction of movement. Raising awareness in diagnostic patients that they emit detectable levels of radiation for a specified time after their procedures is a worthwhile endeavor, and this knowledge may prevent lengthy delays and unpleasant interactions for patients who may trigger radiation alarms. A well-informed patient carrying documentation will certainly be prepared, and this may go a long way in satisfying law enforcement personnel—if they are sufficiently trained in the screening of potentially threatening individuals and the radionuclides routinely used in medical applications. However, as noted in the article, the radiopharmaceutical administration documentation may be false, complete with a telephone number to an accomplice terrorist playing a nuclear medicine professional on the other end. Therefore, it may still be operationally important to detain any individual triggering an alarm until the radionuclide is identified and its amount determined with the appropriate available equipment. A study of the experiences of law enforcement and their recommendations would be extremely valuable.

The alarming of radiological detection equipment does not automatically imply a hazard. According to the State of Florida Department of Transportation (DOT) Radiological Detection Protocol (*5*), many legitimate sources of radiation do not represent an inherent danger, such as radionuclides used in nuclear medicine applications. This is consistent with information provided in the 2003 NRC Information Notice stating that patients treated with these radionuclides not only pose no danger to the public but are legitimately allowed under NRC medical use regulations to be out in public (i.e., these patients are committing no criminal act and certainly can be OWR, or out while radioactive).

The Florida DOT protocol is a sensible procedural course for law enforcement to follow at security checkpoints and was created in conjunction with the U.S. Domestic Nuclear Detection Office (DNDO). The DNDO is an office within the U.S. Department of Homeland Security—established by Presidential Directive on April 15, 2005—that is responsible for the implementation of a preventative radiological/nuclear detection architecture to protect the nation from terrorist threats. According to the Florida DOT protocol, when a detector alarms, the individual should be isolated and questioned. One of the first questions asked is whether this individual had a recent medical procedure involving radioactive material. If the individual's answer is consistent with the actual identity of the source as independently determined by the law enforcement official, who has also been educated about radionuclides routinely used in nuclear medicine applications and who has been trained in the use of the appropriate monitoring equipment, the individual is released.

Patients, then, should be aware of their medical procedures, and that these could trigger alarms, so that they can convey appropriate information to law enforcement in the event of a radiation monitoring alarm. Any documentation patients might have would serve a dual purpose: (a) to remind the patient of the procedure they underwent and the radionuclide received; and (b) to provide a second layer of "comfort" to law enforcement. Notwithstanding a knowledgeable patient and the availability of documentation, it is still likely that law enforcement agents will consider it a security imperative to independently identify the radionuclide responsible for the alarm. Thus, the actual documentation should play a less important role.

The study reported by Katz and Ansari was conducted in collaboration with the NRC and was supported by the Department of Health and Human Services Agency for Healthcare Research and Quality (AHRQ) and the Centers for Disease Control and Prevention. The basis for this data collection is contained in NRC's Temporary Instruction 2800/039, "Information Collection: Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material." One of the stated objectives of this Temporary Instruction was to gather information concerning licensees' implementation of the 2003 NRC Information Notice. AHRQ expressed an expectation that best practices would be identified so that standardized procedures could be developed within the existing regulatory framework. In addition, the study findings were to be presented to the NRC Advisory Committee on the Medical Uses of Isotopes. This is somewhat disconcerting, because the NRC Information Notice required no action, contained little useful information on how to actually do anything, and, as noted above, neglected to call for or describe a sensible standardized procedural course for law enforcement in the event of a radiation detector alarm. Law enforcement

will likely always bear the burden of independently verifying the radionuclide source in such events, but the burden on patients can be minimized if they are aware of and can communicate their own medical procedure information.

In conclusion, AU physicians should be communicating the radiation alarm issue and providing documentation to released patients (therapeutic as well as diagnostic). Although the NRC has provided "information" to licensees that requires no action, it also has created no regulatory requirement to ensure that patients are provided with relevant information or even to ensure an appropriately released patient's compliance with required instructions and documentation. Professional organizations such as SNM and ACNP have taken the lead on this issue and have disseminated more appropriate information to their memberships, along with sample documentation that can be provided to all released nuclear medicine patients. Interaction between professional organizations (and their members) and law enforcement is likely the best course to help minimize patient burdens at radiation security checkpoints.

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**KATZ AND ANSARI RESPOND:** Siegel's and Marcus's concerns about our study design appear to be that relevant nuclear medicine professionals were not adequately surveyed, that only 10% of the surveyed professionals were AUs, and that the study did not differentiate the medical specialty and board certification of the surveyed physicians so that the AU "offenders" can be more specifically identified.

The objective of our study was to examine the range of practices among small and large hospitals and outpatient clinics to identify good practices as well as areas that could be improved. We could not achieve this objective if we had limited the survey to board-certified nuclear medicine AUs.

The interviews were conducted in the context of the NRC's periodic unannounced inspections of each surveyed facility. At each inspection, 1 or more key personnel at the surveyed institutions were asked to provide information about general practices at the facilities they represented. Survey participants were asked if they were personally involved and participated in: (a) informing patients that they would receive radioactive material; (b) making patient release decisions based on radiological criteria; or (c) communicating risk and safety information to patients. The majority of respondents (84%) participated in at least 2 of these activities. Many (41%) participated in all 3 steps.

Although the responsibility for patient communication "officially" rests with the AUs, other health care professionals in their practice are clearly involved in this process. Our objective was to examine the range of those practices as it related to the clearly defined interests of our study. Furthermore, respondents were representing their facilities to the NRC inspectors. In many of the questions, respondents were addressing not merely their own individual duties but the facility procedures about which they were knowledgeable. We believe the diversity of professionals interviewed (RSOs, physicists, nuclear medicine technologists, managerial staff, and AUs) was a strength of our study, not a weakness.

This study was meant as an exploratory study. We described its limitations in our paper. Our own major concern about the study design was that we (the authors) were unable to ask follow-up questions or ask for clarification for some of the ambiguous responses. We also felt that for certain questions, the respondents may have been inclined to present their facilities in the best possible light because they were being asked questions by an "inspector" from a regulatory agency and may have had concerns that a "wrong" answer could adversely affect inspection results.

It was not the goal of our study to evaluate the adequacy of the existing regulation or the degree of compliance. It was certainly not our goal to blame any particular professional community. We submitted our results to *JNM* because it is the leading journal in the field of nuclear medicine with a large readership. Furthermore, SNM has been at the forefront of this issue. We do agree with Siegel and Marcus that the issue of educating and communicating with released nuclear medicine patients concerns many practitioners outside the readership of *JNM*.

We also agree that a study of law enforcement experiences with released patients, documenting their recommendations, would be extremely valuable. In addition, we suggest a survey of released patients to examine the issue from their perspective.

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