tation (*see* "Communications Among Nuclear Medicine Professionals," *Newsline*, this issue). LUNIS is multifarious, with many aspects that are not designed expressly to improve patient outcome, but in the library, users needing assistance may post a clinical case and get a free consultation from a broad range of nuclear medicine colleagues. The system " may help specialist consultation by allowing complex cases to be reviewed by someone at a distance, at virtually no cost," Dr. Henkin said. Potentially perfecting diagnoses can also make nuclear medicine more competitive in the growing health care market crunch.

On another front changes are in the works in governmental policy and insurance practices. Henry N. Wagner, Jr., MD, division chief, Nuclear Medicine, Johns Hopkins Medical Institutions (Baltimore, MD), described a proposal by the new assistant administrator in charge of planning at HCFA, Kathy Buto.

"She is promoting the concept of limited authorization for payments—limiting them to standard applications, initially for a limited period of time" (with the possibility for extension if subsequent experience is favorable), said Dr. Wagner. "I told her this approach would be great, for example, for PET.... HCFA would be more likely to authorize procedures if approved initially in a limited way." Dr. Wagner believes that a more highly planned authorization by HCFA would be analogous to Phase IV data-collecting trials and would mean less delay for getting reimbursement for a new technology. However, Ms. Buto cautioned *Newsline,* "We're just considering an approach and not yet a proposal—we're just at the thinking stage."

Some insurance companies are beginning to examine how nuclear medicine technologies may benefit them by cutting the costs of proceeding with more expensive and possibly unnecessary procedures, which insurance companies usually have to pay for. Richard J. Neeson, president and CEO of Keystone Ventures (Bala Cynwyd, PA) studied a Blue Cross /Blue Shield claims payments database for the real costs of claims paid for cardiac intervention cases, then calculated what the difference in cost would have been if PET scans had been used in each case. He determined that PET would have precluded the need for many of the interventions and so decreased costs. Thus, though an insurer would have to invest a little extra up front for the PET scan, in the long run costs would be less. Elizabeth F. Brown, MD, medical director at Aetna Health Plans (Chicago, IL), encouraged the use of TA—the analysis of a technology's safety and effectiveness. Aetna uses TA in determining coverage for PET scans, though insurance companies like Aetna cannot consistently use cost-effectiveness in making reimbursement decisions because there are so few studies in the literature. Thus, she called for the development of practice guidelines which work for all the sub-specialties, and warned that PET and other high-profile diagnostic imaging would be easy targets in coming cost-cutting campaigns.

"The nuclear medicine community should not be afraid of what's going on if our tests have value," Dr. Royal said. "People always fear change, and prefer the devil they know over the one they don't know." However, "I think we'll streamline our studies, and get the most information for the least cost—no longer the maximum amount of information, but the optimum." The word "optimum" just may sum up the goals of cost-effectiveness—increasing quality while decreasing costs.

Lantz Miller

INSPECTOR GENERAL'S AUDIT: NRC'S MISMANAGEMENT OF MEDICAL MISADMINISTRATION

IG Report concludes the agency has attempted to refine its methodology but lacks compatible databases

AFTER THE *CLEVELAND PLAIN-Dealer* described medical misuse of radiation in December 1992, creating public and congressional outcry, the NRC's Inspector General's Office (IGO) investigated the agency's handling of misadministrations, issuing a report Sept. 7, 1993. Though some observers in the nuclear medicine community have labeled the report a public relations ploy of no consequence, others

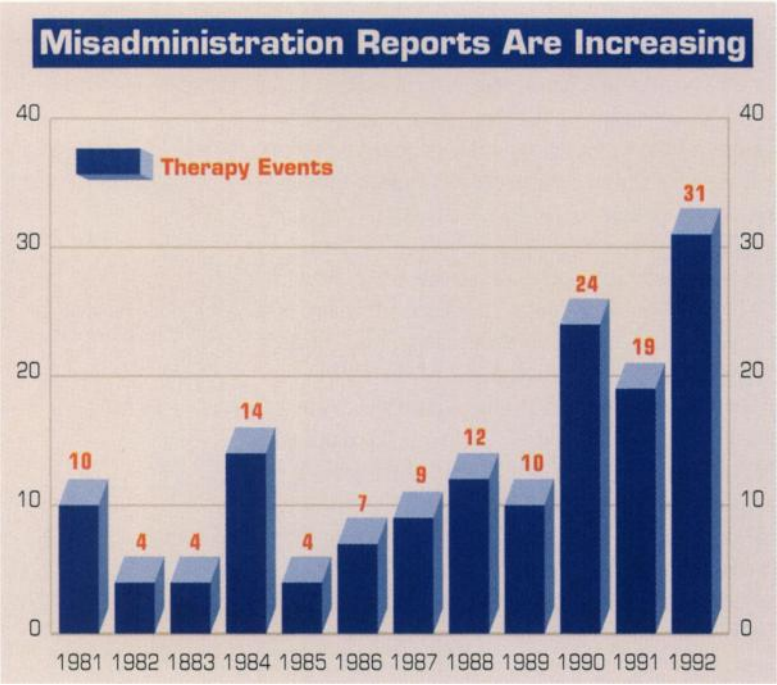


Figure1. IGO's data on increase of NRC's misadministration reports, particularly during 1990-1992.

Source: Office of the Inspector General's Audit Report, "NRC's Management of Misadministration Information is Inadequate," September 7,1993

see it as a pesky example of how government too often solves problems: by suggesting more rules.

"The report won't do anything in itself," said Robert E. Henkin, MD, of the Nuclear Medicine Department, Loyola University Medical Center (Maywood, IL), who serves on SNM's Government Relations Committee and the new Commission on Health Care Policy and has been following the NRC for years. "The problem is not the report but the NRC's response to fix problems by issuing more regulations." Though he grants the validity of the report's finding on how the NRC administers its role, he suspects the agency will fill in the gaps with more stringent reporting rules.

In the report's introduction, the IGO acknowledges that both the *Cleveland Plain-Dealer* stories and a report of a patient's accidentally receiving 1,600,000 rads of radiation for cancer therapy "raised questions regarding NRC's collection, analyses, and management of misadministration information" which the investigation then attempted to answer, since accurate data on misadministrations is key to determining how to prevent accidents. The Commission established the first rules for reporting medical misadministrations of radiation in 1980, and records of such data from all the medical licensees of the 28 Agreement States and the 21 states overseen by the Office of Nuclear Materials Safety and Safeguards (NMSS) were kept from 1981 (Fig. 1). One of the central problems that the IGO uncovered in its investigation of NRC's data management was the sudden jump in misadministration reports in 1990: 1990-1992 exhibited, on average, three times the annual average for 1981-1989. The question is why—and the fact that it is not readily answerable accounts for the allegation that the NRC is not properly maintaining its misadministration data.

As John Glenn, PhD, a health physicist and branch chief of the NRC's Division of Industrial and Medical Nuclear Safety (IMNS), described the situation, the two events spurring the IGO's inspection were not only the *Plain-Dealer* stories but also a Government Accounting Office audit in fall 1992 (published in April 1993), observing a lack of consistency in the agency's data gathering and processing. The GAO found that the "NRC didn't have a single database for determining how many misadministrations there were nationally, for how many led to deaths; there was no consistency between data collection for agreement states and others: the AEOD (Office of Analysis and Evaluation of Operational Data) had data only from some Agreement States," Dr. Glenn said. "The NRC does not have an unimpeachable source for the denominator: should it be the number of patients treated per year in certain modalities? should it be treatment types? For any rate we give, the uncertainty is too great.... We have relied on industry estimates of the number of procedures rather than collecting [these numbers] ourselves.... The IG says we should count it in a consistent, proper way using real not estimated data, and use that to [assess] our regulatory effectiveness."

Specifically, the IGO report faults the NRC for using "outdated information to calculate misadministration error rates," for "continuing to rely on the medical community to estimate the number of therapy procedures," and for "attempting to use federal databases of Medicare patients, and patients admitted to hospitals, to determine the number of procedures performed annually"—while the "NRC acknowledges these databases are incomplete and incompatible." The Quality Management Program (QMP) required NMSS licensees to sample medical administrations annually to identify previously unnoticed misadministrations—although Agreement States did not have to do so until 1995, making data among the 50 states incomparable until then. "The reliability of Agreement State data is questionable because Agreement State licensees have historically reported fewer events than NRC licensees, even though Agreement State licensees are twice as numerous," the report concludes. It also cites other changes NRC made in reporting rules that resulted in confused data. Furthermore, "Because AEOD's methodology masks annual changes in estimated procedures, it also masks changes in error rates." Thus, although NRC staff asserted that recent increases in reports of

misadministrations reflected improved reporting requirements, the report concluded that there was no data or analysis to support the assertion.

Even though the report directly attacks the NRC, the nuclear medicine community is up in arms over the implications about medical practice. "The audit suggests that there is a worrisome trend of increases in reported incidents of misadministration errors in radiation medicine," said William H. McCartney, MD, ACNP president-elect and professor and director of Nuclear Medicine, University of North Carolina Hospital (Chapel Hill, NC), "but in reviewing the data quoted, this is certainly not the case for radiopharmaceutical therapies.... It is apparent in reviewing the audit that radiopharmaceutical therapy misadministration errors are extremely rare, regardless of whose data are utilized." He noted that in 1992 there were four such misadministrations out of 40,000 radiopharmaceutical therapy procedures, and that in general there is a high margin of safety in treating with agents like radioiodine (so that errors greater than 20% do not necessarily mean significant threat to the patient's health).

Carol S. Marcus, PhD, MD, director of the Nuclear Outpatient Clinic at Harbor-UCLA Medical Center (Torrance, CA) and a longtime critic of the NRC's medical policy, questions the IGO's position to even attempt the sort of audit it did. "The job of the IGO is to handle the unethical conduct of employees," such as cheating on an expense account. "What is it doing commenting on a scientific, medical issue?" Dr. Marcus cites her own request that the IGO inspect a matter within the NRC, and the IGO's refusal for two years with the rationale, "'We can't because we're not scientifically able'" to pursue the matter, as she put it. Now, with its audit of the NRC's misadministration management, the IGO has taken on a highly scientific subject. Pointing out the speed with which the *Cleveland Plain-Dealer* received the report, Dr. Marcus questioned whether the IGO's concerns with that publication went deeper than merely prompting the investigation, as the report asserted.

Dr. Glenn contended that, at least as far as his division, IMNS, was concerned, the audit was no concession to public image. "My group is the subject of the audit," he said. "This a genuine independent audit of the function of my office. Our licensees know what it's like to be audited by our inspectors. I know what it feels like to be audited" by the IGO. He described the IGO as an independent watchdog group that examines the actions of the staff and reviews its adequacy in the role of the NRC. He acknowledged that the audit revealed valid comments on the NRC's handling

Excerpts from the IGO's Audit Report:

"NRC's Management of Misadministration Information Inadequate"

TABLE 1. Comparison of NRC and Agreement State Licensee Reported Misadministration in 1991

Licensee Location	AGREEMENT STATES	NRC STATES AND FEDERAL FACILITIES
Number of Licensees	4524	2094
Type of Misadministration		
Therapy	18	19
Diagnostic	402	441

The reliability of Agreement State data is questionable because Agreement State licensees have historically reported fewer events than NRC licensees, even though Agreement State licensees are twice as numerous. For example, Table [1] shows the reporting of misadministrations in 1991 by Agreement State and NRC licensees, indicating that 4,524 Agreement State medical licensees reported fewer events than NRC's 2,094 licensees. NRC officials acknowledge the disparity in the number of reports, and stated it probably results from underreporting by Agreement State licensees....

Our review found that after nearly 13 years of collecting data, significant weaknesses remain with the NRC's management of medical misadministration information.

We recognize that NRC staff base their regulatory decisions on case-by-case reviews and assessments, not administrative trends. However, we believe it is essential for NRC as a regulator to have accurate data to help determine whether program adjustments are needed to better protect public health and safety. The need for timely, accurate data is even greater today than in 1980, because NRC recently changed its criteria so licensees report only the misadministrations of greatest magnitude. Furthermore, even with this change, the number of reported incidents is increasing and NRC staff do not have analyses or data to explain the rise.

NRC has a history of developing outdated and incomplete misadministration data. To its credit, NRC has recently attempted to refine its methodology, but several significant weaknesses remain, including incompatible data bases and incomplete coverage of all patients. However, NRC has not sought to independently verify estimates of therapy procedures supplied by medical societies. Also, NRC's data will not provide a uniform national perspective until after 1995 when Agreement State licensees are required to follow the new reporting criteria.

These problems lead OIG to conclude NRC has not fully met the objective of establishing a mechanism to collect and evaluate data on medical licensees; they also raise questions about relying on NRC's misadministration information to evaluate the agency's overall effectiveness in protecting public health and safety.

on misadministration information and that his office is taking steps to find a workable denominator for the total number of administrations.

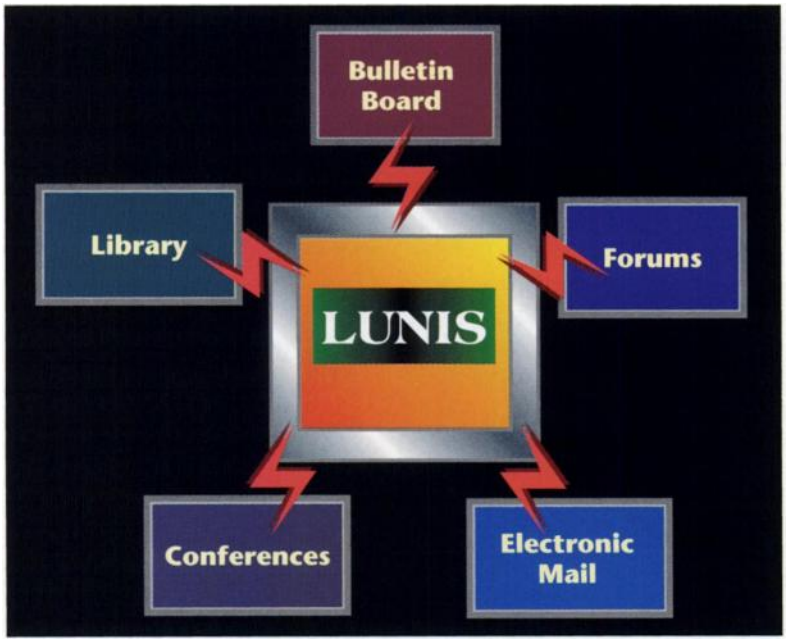
Critics of the report have also expressed concern about its harsh stance on the Agreement States. "It is also suggested that Agreement States are not performing adequately as they report fewer misadministration errors than those supervised by the NRC," Dr. McCartney said. "However, it is at least as likely that the Agreement States simply run their programs more effectively than the larger and more cumbersome NRC and, thus, may have fewer actual misadministrations to report."

Instead of dealing with problems of misadministration information by creating more regulations, critics say, the NRC should seek simpler solutions. "In view of the infrequency of misadministration errors in radiopharmaceutical therapy and the lack of proven negative patient outcomes related to such errors, it would appear that the prior NRC NMSS approach of careful individual review of specific incidents of misadministration was quite adequate," Dr. McCartney said. He recommended that before proposing further regulatory changes, the Commission might await the National Academy of Sciences study that it commissioned on the NRC's regulation of its medical licensees. Rather than rush into new regulations on radiopharmaceutical misadministration, "It seems evident that NRC should allocate its limited resources to other matters which might truly affect public health and safety," Dr. McCartney said. According to Dr. Marcus, many in the nuclear medicine community have been hoping as much for years.

Lantz Miller

COMMENTARY

COMMUNICATIONS AMONG NUCLEAR MEDICINE PROFESSIONALS: ONE APPROACH TO SHARING INFORMATION



INFORMATION IS POWER; LACK OF IT RENDERS one powerless. The ability to quickly transmit information from one location to another—by fax or the "data highway"—has become the hallmark of the 1990's.

Nuclear medicine computers have existed since the late 1960's. It is hard to find a nuclear medicine department today without a computer. Many computers are networked within hospitals to share administrative or clinical information. But few are connected to the outside world.

Beginning in the late 1980's, Loyola University (Chicago, IL) began experimenting with linking the nuclear medicine computers across the country into one communications network. The initial venture undertaken, with Loyola forming the educational base for a commercial nuclear medicine network, was financially unsuccessful. But it received rave educational reviews from the small portion of the nuclear medicine community that assessed it. When financial distress forced the nascent network to close, users asked if a replacement could be developed.

A project was quickly evolved and was presented to the administration of the medical school at Loyola University. We received approval to develop a pilot program to link nuclear medicine computers—both image processing and administrative—around the country into a single communications network. Under the conceptual direction of myself and operational direction of James R. Halama, PhD, assistant professor of radiology and physicist in Nuclear Medicine at Loyola, the Loyola University Nuclear Information System (LUNIS) came online in a limited fashion within two months of the approval.

Unlike commercially based systems, LUNIS was designed