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.