

New NRC Rule Spurred by Radiation Incidents

Motivated by two recent acts of suspected radiation sabotage, the Nuclear Regulatory Commission wants any future events to be reported within 24 hours. Will the new rule prevent intentional misadministrations or just cause unnecessary paperwork?

Nuclear physicians and radiation research scientists alike have sharply criticized a new rule proposed by the Nuclear Regulatory Commission (NRC) which aims to crack down on the criminal misuse of radionuclides. The proposed rule, titled "Reporting Requirements for Unauthorized Use of Licensed Radioactive Material" (10 CFR Part 20; 61 Fed. Reg. 3334, January 31, 1996), would require licensees to notify the NRC within 24 hours of discovering an intentional or allegedly intentional unauthorized use of radionuclides. It would also require them to report within 48 hours any incidents where intentional exposure cannot be ruled out. The rule is in response to two incidents last year in which medical researchers from the National Institutes of Health (NIH) and the Massachusetts Institute of Technology (MIT) ingested the radionuclide ³²P.

At a February meeting with NRC officials, members of the NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI), who usually take the middle ground on new regulations, complained that the rule language is so ambiguous that any unexplained radiation exposure—no matter how minuscule the dose—would need to be reported to the NRC. "We basically said that the 48-hour requirement was ludicrous," said ACMUI Chairman Barry Siegel, MD, a radiologist at the Washington University School of Medicine in St. Louis.

Several Agreement States, dozens of licensees as well as radiology and nuclear medicine organizations filed formal comments with the NRC opposing the rule on the grounds that it is not necessary and its time requirements are too demanding. "The Society of Nuclear Medicine and American College of Nuclear Physicians have taken the position that the rule in its current form should be withdrawn," said David Nichols, associate director of the ACNP/SNM Government Relations Office in Reston, VA. NRC officials have responded by saying they will review the comments and make necessary changes to the rule.

The rule itself is very brief. It merely says that

| Date | Location | Isotope | Reported Dose/Intake | No. of People Contaminated | Agreement State |
|-------|---|------------------|----------------------|----------------------------|-----------------|
| 11/78 | University of California | ³² P | 3-4 mCi | 3 | Y |
| 2/82 | Brown University | ³² P | 157 µCi | 2 | Y |
| 3/83 | Washington University | ¹²⁵ I | 0.360 µCi | 1 | N |
| 8/84 | VA Medical Center (Bronx) | ¹²⁵ I | 524 µCi | 1 | N |
| 3/88 | Albert Einstein Medical Center (New York) | ³² P | 400-800 µCi | 1 | Y |
| 4/88 | Duke University | ³² P | 5.96 mCi | 1 | Y |
| 6/91 | University of California | ¹²⁵ I | 78 µCi | 1 | Y |
| 11/92 | Toronto Canada | ³² P | 1.9 rem | 1 | n/a |
| 6/95 | NIH Bethesda, MD | ³² P | 500 µCi | 27 | N |
| 8/95 | MIT Cambridge, MA | ³² P | 579 µCi | 1 | N |

Source: Nuclear Regulatory Commission

licensees must report intentional or allegedly intentional events by making a telephone call within 24 hours to the NRC and must call the NRC within 48 hours if they are unable to ascertain if the incident was deliberate. There is no mention of a threshold dose and no mention of the word "crime." Three-quarters of the Federal Register notice is composed of various examples of when the rule would or would not be applied. Critics point out that the fact that the rule needs to be explained in terms of specific situations points to the ambiguity of its language.

"This is a typical example of regulatory over-reaction to isolated incidents," said Siegel. "There were two recent bad events, and the NRC is absolutely over-reacting." The events at NIH and MIT grabbed newspaper headlines and spots on the evening news. The first incident occurred at the National Institutes of Health in Bethesda,

MD, in June of last year when a pregnant research fellow, Maryann Ma, PhD, ingested somewhere between 300 and 800 microcuries of ^{32}P . A contaminated water cooler caused slight exposure in 26 other workers. The second incident occurred at the MIT Cancer Research Center in Cambridge, MA last August when a male researcher ingested about 500 μCi of ^{32}P . Both incidents were believed to be deliberate acts of contamination, but investigators still do not know who committed the acts.

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—Sue Gagner, NRC Public Affairs Officer

to report deliberate acts if they are below a certain exposure. While conducting the NIH and MIT investigations, “we realized we didn’t have a system for gathering information on how many intentional instances there are,” said John Glenn, PhD, chief of the radiation protection and health effects branch of the NRC. He said the NRC reporting rule is needed to monitor the actions a licensee is taking in response to the incident, to evaluate the overall security of the facility and to suggest ways to deter incidents from occurring in the future. The NRC could also serve as a middleman if friction develops between the institution and the person who was exposed to the radiation.

In its evaluation of the MIT case, the NRC investigative team found that the NRC has been sending out “mixed messages” with regards to regulations of what needs to be reported. For instance, the NRC requires immediate reporting if the total effective dose equivalent (TEDE) is 25 rem or above, requires 24 hour reporting if the TEDE exceeds 5 rem in 24 hours and 30 day reporting if the TEDE exceeds 5 rem in a year. Glenn emphasized that the NRC needs rulemaking to clarify what should be done if a worker is intentionally exposed to lower quantities of radiation.

Case in point: Glenn said MIT radiation safety officers waited nearly two months before notifying the NRC about the incident. The officers felt they were not compelled by NRC’s rules to comment since the victim’s estimated exposure was calculated to be under 5 rem. Regardless of the exposure, “we’re looking to be notified of any event where radioactive material was used with the intent of one person to harm another,” Glenn explained. “The biggest challenge is to come up with rule language that captures those events without bringing in others.”

Negative Response to the Rule

NRC officials said they received a total of 84 comments about the rule—virtually all of which were negative. Eight Agreement States filed comments opposing the rule with some stating that a need for the rule has not been demonstrated. Other states pointed out that the rule would do nothing to hinder criminal acts and that the NRC should instead focus on improvements that can be made by licensees to prevent such occurrences. Several commenters from university and hospital research facilities took issue with the 48-hour requirement writing that it theoretically could cover every uptake that occurs. “It’s something we have to look at when we write the final rule,” Glenn said. He would not comment on the specific changes that will be made to the final rule which is expected to be published in the Federal Register within the next few months.

NRC licensees who spoke with *Newsline* all agreed their two biggest objections to the rule were the 48-hour requirement for potentially deliberate acts and the no-threshold dose for reporting. Although the 48-hour requirement may be stricken from the final rule, the no-threshold dose will probably remain in place. “That’s precisely the reason for the rule,” said Larry Camper, chief of the medical, academic and commercial use safety branch of the NRC. “The current NRC rule has a threshold.”

In the proposed rule, the NRC estimated that a total of 20 incidents would be reported each year for intentional or allegedly intentional exposures. (However, data compiled by the NRC shows these instances are far more rare. See chart on page 15N.) The rule also estimated that 20 hours would be required to determine the cause of the event, prepare the report, complete the management review and make a telephone call to the NRC operations center. At \$116 per hour, they estimated the total aggregate cost would be \$46,400 per year for licensees. In comments to the NRC, the state of Illinois said this was “a gross underestimate” in lieu of the time and money spent by licensees on the MIT and NIH investigations.

Could the Rule Actually Cause More Crime?

Although the proposed rule discusses only the need to report an incident, an underlying concern among licensees is the NRC investigation that would follow. They question why the NRC is needed since the police and institution radiation safety officers usually conduct their own investigations. “If someone is poisoned by a prescription drug, does the FDA come in to investigate? No, it’s the police,” said Mark Rotman, DPh, a nuclear pharmacist at the NIH. He pointed out that many chemicals in research labs are more easily available and a lot

more toxic than radioactive substances. "It's questionable whether these contamination events were meant to produce any real harm," Rotman said. In the MIT incident, the NRC report concluded that the researcher received an exposure of just under 5 rem and that "no symptoms or acute effects should be observed from an intake of this level." The exact amount ingested by the NIH researcher is still under investigation.

Instead of inflicting physical harm, the criminal may have an ulterior motive: to sidetrack a colleague's research. "The resulting investigation can remove both the accused and the victim from their work for six months," Rotman said. Thus if the NRC begins sending out inspection teams for every alleged deliberate contamination, he argued, the agency could be playing into the hands of those committing the crimes.

A Thirst for Media Coverage?

Licensees asserted that the rule's effects could extend even further. The media coverage that the NRC conjures up by issuing press releases may trigger copycat crimes. Individuals who hear about the criminal use of radioactive materials in the news could carry out a similar act in a desire for media attention for themselves or as a way to sabotage a researcher. The problem lies in the NRC's policy of sending out statements to the media almost immediately after being informed about an incident.

Case in point: On June 30, 1995, the NIH informed the NRC that it was investigating a possible intentional contamination of a pregnant researcher. On July 3, the NRC issued a press release outlining the details of the investigation. Before the news was made public, "I urged [the NRC] not to issue a press release due to the possibility of interfering with a criminal investigation," said Shawn Googins, MS, CHP, deputy radiation safety officer and chief of the technical services section of the radiation safety branch at NIH. After he was assured that a press release would not be released, he said, one was issued anyway containing "numerous factual errors."

The NRC does not have a formal policy of determining if and when a press release should be issued, according to NRC public affairs officer Sue Gagner. "We release information about an event when we think it will be of interest to the public," she said. When asked if the NRC is careful not to release details while a criminal investigation is ongoing, she responded, "we are aware of privacy issues, but we don't send our press releases to the FBI to look at."

Considering that the NRC is a government agency, the "openness" policy appears to make

sense. The public does have a right to know about these incidents. Moreover, the U.S. government probably wants no air of secrecy when it comes to informing citizens about intentional acts of radiation exposure.

Some, however, question the NRC's true motives. "The NRC's mission has been highly questioned by the Institute of Medicine's report, so NRC officials are looking for ways to perpetuate the agency's existence," said Rotman.

"If they can orchestrate a media event, they can bolster their position."

Googins experienced firsthand the media frenzy caused by the NIH incident. While he was heading the team collecting and analyzing urine bioassays to determine the exposure to Ma and her 26 co-workers, he was also receiving numerous calls from the press.

Frank Masse, the chief radiation protection officer and director of radiation programs at MIT, is also familiar with the NRC and what he calls their "visibility issue." He contended that a major reason the NRC sent in an inspection team to investigate the MIT incident was for the media exposure. The NRC issued several press releases regarding their investigation at MIT. What's more, NRC officials held a press conference at MIT after completing their investigation and instructed Masse to find a room which could accommodate television cameras.

Even more troubling is the assertion by Masse and Googins that the NRC's investigation teams interfere with the criminal investigations conducted by the police and research institutions. "I have no doubt that if [the NRC] had come in on day 2 instead of day 60, we could not have done the job we did in determining the doses," said Masse. "An NRC team was immediately at the NIH site and to this day no one knows what the dose to Dr. Ma was."

Googins concurred. "The NRC's continual presence and their demand for raw data and constant explanations of basic radioactivity measurement techniques interfered with the work of myself and my staff."

No one knows what impact the new rule will have until it goes into effect. Siegel said if the rule is published as proposed then licensees might well "inundate the NRC with telephone calls reporting the slightest event such that [the NRC] will never be able to figure out which acts to investigate." Given that the final rule probably will be softened but not scrapped, "we'll just have to find a way to live with it," he said.

—Deborah Kotz

"If [the NRC] can orchestrate a media event, they can bolster their position."

—Mark Rotman, Nuclear Pharmacist at NIH