History of the NRC's Misadministration Reporting Rule

The US Nuclear Regulatory Commission's (NRC) predecessor, the Atomic Energy Commission (AEC), first proposed a misadministration reporting rule in response to an August 1972 Government Accounting Office (GAO) report on AEC's program for fuel cycle and byproduct materials licensees. According to that report, "From February 1961 through April 1972, 20 wrong doses or overdoses were brought to AEC's attention.... These cases involved human error. GAO recognizes that, even with improved regulations, the possibility of such errors will not be eliminated. Nevertheless GAO believes that, to strengthen AEC's controls over the use of radioactive materials, AEC should: define in its medical licenses or regulations the activities that may be delegated by physicians and those that may not; require physicians to determine that technicians have been properly trained for their duties; and require that wrong doses or overdoses be reported to AEC." In its summary of this matter, GAO noted that AEC had responded that "this recommendation was under study and would be reviewed by its Advisory Committee on the Medical Uses of Isotopes." AEC explained that it was necessary to study accepted medical ethics of the physician-patient relationship and the possible consequences of a government agency's interjecting itself into this relationship.

In March 1973, AEC published a proposed rule, including a proposed misadministration reporting requirement, that addressed GAO's concerns. Recognizing that there may be some disagreement with the proposed reporting requirement, AEC noted that 10 CFR 20.403 required licensees to notify the Commission of incidents involving the exposure of individuals to excessive radiation, but that medical licensees were excepted by 10 CFR 20.107, which said that nothing in the regulations shall be interpreted as limiting the intentional exposure of patients for medical care. The proposed rule would have required licensees to notify the AEC of misadministrations, and to notify patients if a demonstrable effect may result from the misadministration unless notifying the patient might be contrary to the patient's best interest.

In May 1977, the NRC (established as AEC's regulatory successor in 1975) proposed a teletherapy calibration requirement and a requirement that licensees report to the referring physician and the NRC if calibration measurements indicated that a delivered dose differed from a prescribed dose by more than 10%. These proposed requirements were issued in response to the 1976 Riverside Hospital incident, in which 400 patients were overdosed because of an improperly calibrated cobalt-60 teletherapy unit. As a separate action, the NRC published in March 1978 a proposed "Medical Policy Statement" that, in part, called for public comment on the extent to which the NRC should regulate the medical use of byproduct material for the purpose of patient protection. In the proposed policy, the NRC noted, "The purpose of a misadministration reporting requirement is to allow the NRC to investigate the incident, evaluate the corrective action taken by the licensee to minimize the chance for recurrence, and, if other licensees could make the same errors, begin generic corrective action which would, as a minimum, inform other licensees of the potential problem." (The final Medical Policy Statement was published in February 1979.)

In July 1978, the NRC withdrew AEC's 1973 proposed rule and proposed instead that all licensees keep a record of each misadministration and, if it were a therapy misadministration or a diagnostic misadministration that might cause "a clinically detectable adverse effect," report it to the NRC, and also to the patient or guardian unless the referring physician were to intervene.

The proposed rule drew several comments. Most of the commenters characterized the rule as an unprecedented intrusion into medical practice that would cause undue alarm and unwarranted malpractice suits. The NRC responded in the analysis of comments that accompanied the final rule by quoting a 1979 GAO report that said "...requiring medical licensees to report misadministrations to NRC is not an intrusion into medical practice. This is clearly consistent with NRC regulatory responsibilities and a necessary part of an effective nuclear medicine regulatory program. Without this kind of feedback on incidents affecting the public health and safety, the NRC cannot be sure it is adequately regulating the possession and use of nuclear materials in medical practice." In response to queries, representatives of the insurance industry reported to the NRC, "It is simply beyond our competence to quantify the effect on medical malpractice rates of your proposed rule. ...We frankly doubt that anyone can gauge the likely effect of such a rule...."

Most important, though, was NRC's response to comments that "clinically detectable adverse effect" was an unclear trigger—NRC changed the rule to require a quarterly report of *all* diagnostic misadministrations in addition to the prompt report of therapy misadministrations. The final rule, published May 14, 1980, became effective on November 10 of that year.

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