《招待講演》

Handling of Therapeutic Radionuclides and Radioactive Waste in USA

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In the United States (US) there are two US government agencies that regulate radiation safety, the NRC (Nuclear Regulatory Commission) and the EPA (Environmental Protection Agency).

The NRC is responsible for laws to ensure the safe use of radioactive materials in medicine (Publication 10 CFR Part 35) with additional responsibility for the protection of the general public and occupational workers (nuclear medicine physicians and technologists) (Publication 10 CFR Part 20). The EPA's role is to protect the public and environment from potential harm from radiation exposure.

Usually, the EPA sets standards and the NRC implements them. Understanding US regulations is complicated by the fact that there are other agencies and organizations that also play a role in regulating the medical use of radiopharmaceuticals. For example, the NRC has permitted 30 of the 50 states in the US (so called "agreement states") to regulate locally their use of radioactive materials. The states often use NRC requirements but may impose additional requirements.

The mix of regulatory rules and recommendations is further complicated by the use of additional guidelines from the International Commission on Radiological Protection (ICRP) and The National Council on Radiation Protection and Measurement (NCRP). In the US NRC policies often reflect ICRP recommendations (especially ICRP Pub. #26, 1977) but not as rigorously as they are applied in non US countries.

The Society of Nuclear Medicine (SNM) together with individuals of the nuclear medicine community have continued to work with the NRC for many years to try and achieve revisions to the US regulations which more realistically reflect a true "risk-based assessment" especially considering the very low risk of diagnostic radiopharmaceuticals. This has resulted in recent significant regulatory changes. For therapeutic radiopharmaceuticals there have also been significant changes that now permit radionuclide therapy (with I-131, P-32, Sr-89) on an outpatient basis.

The goals of this lecture include: (1) to provide a review of the history of US regulations on the medical use of radiopharmaceuticals (2) to review the role that organized medicine can play to accomplish meaningful change in government regulations, and (3) to give examples of how relatively simply practice guidelines now permit patients to receive outpatient radionuclide therapy.