CMS Reopens Comment Period for PET National Coverage Decision

In September, the Centers for Medicare and Medicaid Services (CMS) reopened the public comment period for the PET National Coverage Decision (NCD) to address public comments that the current coverage framework—which requires cancer-by-cancer consideration of diagnosis, staging, restaging, and monitoring response to treatment—should be replaced by a more general policy for all oncologic ^{18}F-FDG PET imaging. The comment period was reopened so the public could give evidence-based data and/or literature on the use of ^{18}F-FDG PET imaging for other solid tumors and suggestions for possible alternatives to the current coverage framework. SNM has been working closely with all the stakeholders involved to jointly present at the last CMS Medicare Evidence Development and Coverage Advisory Committee meeting and to develop educational documents to help PET facilities and referring physicians turn in substantive comments to CMS on the issue. In response to this announcement, the SNM and the National Oncologic PET Registry (NOPR) developed and submitted comments, now posted on the SNM Web site (http://interactive.snm.org/index.cfm?PageID=277).

SNM Responds to NRC and NRDC on LEU Change

Also in September, SNM filed comments with the Nuclear Regulatory Commission (NRC) in response to a petition for rulemaking filed by the Natural Resources Defense Council (NRDC). The NRDC has requested that the NRC amend the regulations that govern domestic licensing of production and utilization facilities and special nuclear material to establish a date on which the NRC will no longer license the use or export of highly enriched uranium (HEU) except for restricted use by a few specialized facilities. The NRDC believes that the amendment is needed to protect the public from potential exposure to an improvised nuclear explosive device made with HEU and used by terrorists.

The SNM recommended that the NRDC's petition be denied for the following reasons. Forcing a change from HEU to low-enriched uranium (LEU) will put patients at risk because of the inevitable delay in production of much-needed radionuclides, such as ^{99m}Tc. No large-scale, commercial processes using LEU targets for medical isotopes have been developed or implemented. The technology must first be proven to be robust and reliable, and a transition period will be required. Moreover, the system must be able to provide commercial quantities of ^{99}Mo (thousands of curies per week, every week). If unable to do so, the ultimate consumers of ^{99m}Tc—patients—will be put at risk.

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Second, the financial impact of forcing a change from HEU to LEU has been underestimated by the NRDC. Although it is technically feasible to produce ^{99}Mo from LEU, production would not be commercially viable without substantial federal subsidies. In addition to structural and technological changes that must be made, approval will have to be obtained from the Food and Drug Administration (FDA). Any new technology will not be considered complete until it receives both FDA and NRC approval, which is expensive both in terms of time and expected fees associated with the application process. It has been estimated that the cost of verifying and generating approval for a different process will be in the millions of dollars.

Third, the environmental impact of such a switch has also been underestimated by the NRDC. A switch to LEU will not only increase the amount of plutonium produced as a result of the increase in ^{238}U in the target that will capture neutrons production but will also increase the amount of radioactive waste produced. Both the plutonium and the radioactive waste will have to be disposed of properly, further increasing costs, which will ultimately be passed on to the patient.

Finally, SNM recommended that the NRC consider reopening the comment period and also delay its decision until the recommendations of the National Academy of Sciences report on *Medical Isotope Production Without Highly Enriched Uranium* (to be released soon) can be taken into consideration.

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