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The search for consistency in the manufacture of PET radiopharmaceuticals

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Nuclear Medicine is the specialty of medical imaging, which utilizes a variety of radionuclides incorporated into specific compounds for diagnostic imaging and therapeutic applications. During recent years, research efforts in this discipline have concentrated on the decay characteristics of particular radionuclides and the design of unique radiolabeled tracers necessary to achieve time-dependent molecular images.

Various oncology applications have utilized specific PET and SPECT radiopharmaceuticals, which have allowed an extension from functional process imaging in tissue to pathologic processes and nuclide directed treatments. One of the most widely recognized advantages of positron emission tomography (PET) is its use of the attractive, positron-emitting biologic radiotracers that mimic natural substrates. However, a major disadvantage is that these substances are relatively short-lived and unable to be transported great distances. At this time, economic considerations and regulatory guidelines associated with the creation of a PET facility, as well as the operational costs of maintaining both the facility and the necessary procedural documentation, continue to create interesting strategic dilemmas.

This commentary will focus on the current approach and anticipated impact of pending regulations, which relate to the manufacture and formulation of a variety of PET radiopharmaceuticals used in clinical research and patient management at Memorial Hospital.