Dr. Christopher Palestro
Chairman of the Advisory Committee on the Medical Use of Isotopes
Nuclear Regulatory Commission

Dear Dr Palestro,

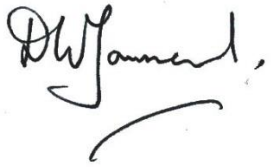
I am writing to you as co-inventor of the combined PET/CT scanner (along with Dr Ronald Nutt) that brought PET scanning into mainstream radiology for imaging oncology patients. The device became commercial in 2001 and now there are around 5000 such scanners worldwide. Over two million PET/CT scans are currently performed in the USA annually. Increasingly, PET is being used to monitor and guide therapy in cancer patients, a procedure that requires measuring the uptake of the radiopharmaceutical by the tumor. Such quantitation requires that the injection of the radiopharmaceutical be performed efficiently (without infiltration) and reproducibly.

For the last several years I have been a non-compensated scientific consultant for Lucerno Dynamics, the company that manufactures a simple device capable of monitoring the radioactive injection in PET studies. Since the device can provide a time-activity curve of the presence of the radiopharmaceutical near the injection site before the patient is imaged, it is now possible to reliably estimate the local radiation dose to the tissue in the event of an infiltration. **Given this new information I would respectfully request that infiltrated injections that exceed the reporting limit are mandated to be reported, and that the current exemption from reporting such infiltrations be removed.** While infiltrations in PET and other nuclear medicine procedures may be rare, a significant infiltration may deliver a high local radiation dose and it should be reported. Such infiltrations critically affect the integrity of the imaging study and may have consequences for the management of the patient.

As a final point, in addition to the over two million PET scans performed each year in the USA, some 40 – 45 million nuclear medicine studies are performed, also requiring a radioactive injection to the patient. Thus, even a low rate of infiltration potentially represents a radiation protection issue for a significant number of patients. The Lucerno device could also provide such a monitoring service for these nuclear medicine studies such that infiltrations which exceed the reporting limit be identified ***and reported***.

If you have any questions or require further information, please do not hesitate to contact me.

Sincerely,



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