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General Comment

See attached file(s)

Attachments

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I believe Proposed Revision 2 to Regulatory Guide 8.39 DG-8061 <u>should not be accepted as written.</u> The calculation method outlined in the guide is overly complex and burdensome and is not clinically realistic. **The existing guidance should be maintained and addendums for new radionuclide therapies can be added as needed.** An entirely new strategy for calculating potential public dose from radiopharmaceutical therapy patients was unwarranted.

I am a consulting medical physicist with 37 years of experience. Nine of those years were working as a hospital based radiation oncology physicist where I administered or assisted with the administration of radiopharmaceutical therapies for thyroid cancer(NaI-131) and lymphoma(Y90). I currently assist with the therapeutic administration of Y90 microspheres. I currently consult with Nuclear Medicine Technologists in medium and small medical facilities who will be the clinical personnel attempting to follow this new guide. Most of your comments will be received from the larger institutions with the resources to review the proposed regulations and submit responses. I am responding with the perspective of the staff in small- to medium-sized rural hospitals who have a very different view of the healthcare landscape.

Unnecessary. This revision to the existing regulatory guidance on the release of patients following radiopharmaceutical therapies is reportedly an attempt to correct a supposed public safety issue. I have seen no evidence of any harm caused by the treatment of patients following the existing guidance.

Appropriate medical care should not be only for those who can travel to receive treatment. This overregulation would create another example of health care inequity. Deciding whether or not to offer these beneficial radiopharmaceutical therapies is a real discussion happening among hospital administrators.

Radiopharmaceutical therapy for thyroid cancer is given to decrease the likelihood of recurrence and to treat known disease. The therapy is easily tolerated by patients and currently is relatively inexpensive. This outpatient procedure is currently available in most medium to large medical centers in Michigan which are located in the medium to large cities. Already, many small hospitals in Michigan no longer have the physician expertise to perform radiopharmaceutical therapies and the patients are referred to the medium to large medical centers. Patients who do not live near the larger medical centers or university hospitals may well be forced to choose between travelling even longer distances to receive treatment or forego treatment altogether if more hospitals stop offering these therapies.

Prior to 1992 when patients were hospitalized for radiopharmaceutical NaI-131 therapies exceeding 30 mCi, it was common for patients to be forced to wait for treatment until the hospital could find an inpatient room where they could be housed in accordance with all regulatory requirements. Now it is common for a patient to be treated as an outpatient immediately after their diagnostic scanning is completed. This is a clinical and emotional benefit to the patient. Yet the guidance seems to be advocating for holding/admitting patients post therapy until they reach Tier 1 remaining activities. Hospital administrators are concerned about the reimbursement for these admissions.

Nuclear Medicine Technologists tell me that don't know how they will implement the proposed guidance and they suggest no longer offering the radiopharmaceutical therapies due to the staffing requirements.

Many Nuclear Medicine departments in Michigan are struggling just to perform diagnostic testing due to staffing shortages. The amount of data collection and calculations needed for the Tier 2 patient specific in the proposed guide will be a time burden on Nuclear Medicine staff. Few hospitals in Michigan have medical physicists on staff. Most are assisted with regulatory compliance by consulting medical physicists. The guidance and the webcast discussions frequently referred to having the hospital physicist perform the patient specific calculations. This is not a realistic scenario outside of the larger or university medical centers.

The calculations are complex requiring the licensee to determine the following factors for each patient otherwise they are to use overly conservative factor values of 1.

- Biokinetic modifying factors requiring multiple patient measurements
- Occupancy modifying factors
- Geometry modifying factors using line-line, point-line, or point-point geometry
- Attenuation modifying factors accounting for photon scatter, buildup, and absorption for patient thicknesses.

Nuclear Medicine Technologists who will be responsible for performing the patient specific calculations find the increased burden of data collection and complex calculations overwhelming. The Tier 2 calculations require patient specific biological clearance data. This will require additional testing for every patient which involves additional patient visits to obtain measurements. The existing guidance uses average retention/clearance values accumulated over years of experience to simplify the equations for NaI131. This was discarded in the proposed guidance.

Additionally, *Section 6 Sources Separated from the Patient* illustrates a lack of clinical realism. This section suggests that licensees must have preventive measures in place to ensure that public dose limits are not exceeded if an implant source becomes dislodged after the patient's release. A suggested preventive measure is to label the source. I am not aware of any implant sources that are large enough to accommodate a useful label.

In conclusion, my greatest concern about implementing the proposed guidance is that it will likely deprive some patients of this beneficial type of treatment.