

LETTERS TO THE EDITOR

ADDITIONAL RADIATION SAFETY CONCERNS INVOLVING SODIUM IODIDE-131 CAPSULES

To the Editor: The authors Michael Hackett, et al. (1) are to be congratulated on finding radioactivity on the absorbent packing materials of ¹³¹I capsules. Apparently there is some radioactivity on these materials and some precaution may be warranted in subsequent handling. While I read their article with great interest, I do have a concern about their methodology and conclusion.

Lederer, et al. (2) identified that 0.6% of the decay ¹³¹I results in a daughter product ^{131m}Xe. Hidalgo (Hidalgo JU, *personal communication*, 1995) found that most radioactivity present in the air space in selected containers of liquid ¹³¹I had a gamma ray energy at approximately 164 keV and concluded that the gaseous radioactivity in the containers was mostly ^{131m}Xe. Measurements by Hackett, et al. (1) were made in a dose calibrator and therefore could not demonstrate whether the radioactivity was ¹³¹I or ^{131m}Xe.

Since there is a considerable difference in the apparent risk of ¹³¹I and ^{131m}Xe (10 CFR20, Appendix B, Tables 1 and 2), it is most important to verify which radionuclide(s) is actually present in the packing material.

I strongly urge the authors to determine fractionally which radionuclides are present and report their findings as soon as possible. Their hospital's physicist may be interested in assisting with their work.

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- Lederer CM, Hollander JM, Perlman J. *Table of isotopes*, 6th ed. New York, NY: John Wiley and Sons, Inc; 1967:277.

Reply: We appreciate Dr. Ficken's comments concerning our recent article (1). He has brought up some valid points that were not addressed, ¹³¹I does have a radioactive daughter, ^{131m}Xe, and the method we utilized to assay the absorbent (in a dose calibrator) cannot distinguish between the two radionuclides.

Initially, when this investigation was started, we decided that ^{131m}Xe would not contribute greatly to the

measurements due to its low yield of only 1.0% (2) of ¹³¹I decay. We assumed that there was only a short time from the ¹³¹I capsule production to our use, therefore, only a minimal amount of ^{131m}Xe would be present. Upon further investigation, we found this assumption was wrong. The ¹³¹I capsules that we evaluated are manufactured 11 days prior to the calibration date (17 days prior to the expiration date). This can result in a considerable amount of ^{131m}Xe depending on the initial activity of ¹³¹I and the time period from production to receipt of the ¹³¹I capsule. Table 1 summarizes estimated ^{131m}Xe amounts for the ten ¹³¹I capsules in our original article. These estimates are based on the following Bateman equation (3):

$$A_d(t) = A_p(0)(0.01086)(e^{-\lambda_p t} - e^{-\lambda_d t})(\lambda_d)/(\lambda_d - \lambda_p),$$

where $A_d(t)$ is the estimated activity of ^{131m}Xe at time of use, $A_p(0)$ is activity of ¹³¹I at the time of production (midnight of the day of manufacturing to give the highest estimated starting activity), 0.01086 is the branching fraction for ¹³¹I decay to ^{131m}Xe (from Packard Instrument Co., RadDecay software version 3), t is the time in days from manufacturing to use, λ_d and λ_p are the decay constants for ^{131m}Xe and ¹³¹I, respectively, and this assumes that there was no ^{131m}Xe present in the ¹³¹I capsule when it was first manufactured.

To determine the amount of ¹³¹I and ^{131m}Xe in the absorbent, two additional ¹³¹I capsule shipments were evaluated using a similar dose calibrator (same manufacturer) used in the original work and a thyroid uptake probe with a multichannel analyzer. The glass bottle that housed the ¹³¹I capsule and the absorbent was opened in a fume hood and the ¹³¹I capsule was promptly removed and shielded. The absorbent was removed

TABLE 1
Estimated Xenon-131m Production from Original
Iodine-131 Capsules

| No. | Estimated ¹³¹ I activity at time of manufacture MBq (mCi) | No. of days from manufacture to use | ¹³¹ I capsule activity at time of use MBq (mCi) | Estimated ^{131m} Xe activity at time of use MBq (μCi) |
|-----|--|-------------------------------------|--|--|
| 1 | 74.0 (2.0) | 3 | 55.5 (1.5) | 0.13 (3.4) |
| 2 | 199.8 (5.4) | 11 | 74.0 (2.0) | 0.64 (17.2) |
| 3 | 299.7 (8.1) | 10 | 125.8 (3.4) | 0.94 (25.3) |
| 4 | 199.8 (5.4) | 3 | 151.7 (4.1) | 0.33 (9.0) |
| 5 | 499.5 (13.5) | 11 | 196.1 (5.3) | 1.59 (42.9) |
| 6 | 399.6 (10.8) | 8 | 203.5 (5.5) | 1.16 (31.3) |
| 7 | 699.3 (18.9) | 7 | 388.5 (10.5) | 1.92 (51.8) |
| 8 | 1994.3 (53.9) | 11 | 740.0 (20.0) | 6.36 (171.8) |
| 9 | 4987.6 (134.8) | 14 | 1539.2 (41.6) | 16.21 (438.0) |
| 10 | 9971.5 (269.5) | 14 | 3108.0 (84.0) | 32.42 (876.1) |

TABLE 2
Estimated Xenon-131m Production from Two Additional
Iodine-131 Capsules

| Capsule | Estimated ¹³¹ I activity at time of manufacture MBq (mCi) | No. of days from manufacture to use | ¹³¹ I capsule activity at time of use MBq (mCi) | Estimated ^{131m} Xe activity at time of use MBq (μCi) |
|---------|--|-------------------------------------|--|--|
| A | 699.3 (18.9) | 11 | 270.1 (7.3) | 2.23 (60.2) |
| B | 399.6 (10.8) | 7 | 218.3 (5.9) | 1.10 (29.6) |

TABLE 3
Absorbent Measurements on Dose Calibrator (DC) and Thyroid Uptake Probe (TUP)*

| | Initial measurements | | | After being open 1 hr | | |
|---|--|--------------------------------------|--------------------------------------|--|--------------------------------------|--------------------------------------|
| | DC assay on ^{131m} Xe setting | DC assay on ¹³¹ I setting | TUP count in ¹³¹ I window | DC assay on ^{131m} Xe setting | DC assay on ¹³¹ I setting | TUP count in ¹³¹ I window |
| | A | B | C | D | E | F |
| A | 1.95 (52.6) | 1.44 (38.8) | 0.46 (12.4) | 0.59 (16.0) | 0.44 (11.8) | 0.44 (12.0) |
| B | 0.81 (21.9) | 0.60 (16.3) | 0.16 (4.4) | 0.22 (5.9) | 0.16 (4.3) | 0.16 (4.3) |

*Measurements are in MBq (μ Ci) and TUP activity is based on ¹³¹I standard of known activity.

and placed into a glass tube that was immediately capped with a rubber stopper. Assays of the absorbent were made in the dose calibrator on the manufacturer's settings for ¹³¹I and ^{131m}Xe. The absorbent was counted in a thyroid neck phantom at a distance of 27 cm from a standard thyroid uptake probe. Using a multichannel analyzer, counts were obtained under the ¹³¹I 364-keV gamma peak using a 20%-window. An ¹³¹I standard capsule of known activity was counted using the same parameters as the absorbent. The absorbent was assayed and counted again approximately 15 to 35 min after the initial measurements and no appreciable leakage had occurred. The absorbent was removed from the sealed glass tube for approximately 1 hr in a fume hood. After this time, it was placed back into the glass tube, and again assayed and counted.

Tables 2 and 3 summarize the data from both additional absorbents. The ¹³¹I activity measured by the thyroid uptake probe initially and after 1 hr of being open (columns C and F in Table 3) was approximately the same as the dose calibrator assay after 1 hr of being open (column E in Table 3). This demonstrates that ¹³¹I remains trapped in the absorbent while ^{131m}Xe escapes when exposed to open air. From this data, the initial ^{131m}Xe activity in each absorbent can be estimated using the dose calibrator measurements on the ^{131m}Xe setting. To calculate this activity, subtract the assay after one hour of being open (¹³¹I only) from the initial assay (¹³¹I and ^{131m}Xe) (the difference between columns A and D in Table 3). The initial estimated ^{131m}Xe activity in each absorbent was 1.35 and 0.59 MBq (36.6 and 16.0 μ Ci), respectively. From this, a calibration factor

TABLE 4
Estimated Iodine-131 and Xenon-131m Initial Activity in Original Absorbents*

| No. | Initial assay on ¹³¹ I setting | Actual initial ¹³¹ I activity | Estimated initial ^{131m} Xe activity |
|-----|---|--|---|
| | A | B | C |
| 1 | 0.07 (2.0) | 0.01 (0.4) | 0.08 (2.1) |
| 2 | 0.75 (20.3) | 0.38 (10.2) | 0.48 (13.1) |
| 3 | 0.60 (16.2) | 0.07 (2.0) | 0.68 (18.5) |
| 4 | 0.22 (6.0) | 0.06 (1.7) | 0.21 (5.6) |
| 5 | 0.48 (13.0) | 0.17 (4.7) | 0.40 (10.8) |
| 6 | 0.94 (25.3) | 0.18 (4.8) | 0.99 (26.7) |
| 7 | 2.23 (60.2) | 1.48 (40.0) | 0.97 (26.3) |
| 8 | 5.08 (137.2) | 0.90 (24.3) | 5.43 (146.8) |
| 9 | 11.95 (323.0) | 1.48 (40.0) | 13.61 (367.9) |
| 10 | 18.76 (507.0) | 3.70 (100.0) | 19.58 (529.1) |

*Measurements are in MBq (μ Ci).

($\times 1.3$) can be determined to estimate the ^{131m}Xe activity measured on the ¹³¹I dose calibrator setting taking into account the known activity of ¹³¹I. This can be calculated by dividing the initial ^{131m}Xe estimated activity in the absorbent by the difference (on the ¹³¹I setting) of the initial assay (¹³¹I and ^{131m}Xe) and the assay after 1 hr of being open (¹³¹I only) (the difference between columns A and D divided by the difference between columns B and E in Table 3).

Given this new data, the original article's assays on the dose calibrator after the initial rapid decrease in measurements should represent the ¹³¹I activity present in the absorbent (column B in Table 4). The initial ^{131m}Xe activity in the absorbent (column C in Table 4) can be estimated by subtracting the estimated ¹³¹I activity from the initial assay on the ¹³¹I setting and then multiplying by the above calibration factor (the difference between columns A and B from Table 4 multiplied by 1.3).

The above additional data and the activity estimates made from our article still demonstrate potentially high amounts of ¹³¹I contamination, up to 3.7 MBq (100 μ Ci), within the absorbent though not as high as originally reported due to the presence of ^{131m}Xe. Since ¹³¹I is retained in the absorbent and it is ^{131m}Xe that is released, this would pose a lesser radiation safety concern than initially reported (i.e., a lower chance of ¹³¹I intake by the staff). Though this may be the case, ALARA principles should still be used when handling ¹³¹I capsules. We feel that ¹³¹I capsules should be vented in a fume hood before they are assayed to remove the ^{131m}Xe gas that is produced by ¹³¹I decay and any volatile ¹³¹I that may not have been trapped in the absorbent. Additionally, the absorbent should be treated as radioactive waste and should not be included when assaying ¹³¹I capsules.

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MICROWAVE VERSUS RECON-O-STAT™ FOR PREPARATION OF TECHNETIUM-99M-SESTAMIBI: A COMPARISON OF HAND EXPOSURE, RADIO-CHEMICAL PURITY AND IMAGE QUALITY

To the Editor: We read with interest the article by Porter and Karvelis (1) regarding the use of the Recon-o-Stat™ thermal controller (model DMP150, DuPont Pharma, Billerica, MA) to prepare ^{99m}Tc-sestamibi. In comparison with the microwave oven heating method (2-4), the authors concluded that the Recon-o-Stat method significantly reduced the hand exposure to the preparer of Cardiolite® (DuPont Merck Pharmaceutical Co., Billerica, MA) (1). Due to the fact that the Recon-o-Stat method does not require the reaction vial to be taken out of the tungsten vial shield during the 10-min heating and cooling cycle period, the radiation exposure to the hands of the preparer undoubtedly would be lower than with the other methods (e.g., microwave oven heating, boiling water bath and heating block), which all require some hand maneuvering of the ^{99m}Tc-sestamibi vial. Since the microwave oven heating method involves more handling of the vial with the hands (i.e., attachment and removal of the styrofoam cover, placement and retrieval of the vial in a screw-cap plastic container), finger exposure using the microwave heating method would probably be the highest.

Radiation Exposure versus Clinical Benefits

However, the use of a microwave oven in the preparation of ^{99m}Tc-sestamibi should not be discouraged by this report. Technetium-99m-sestamibi is very useful to quantify the amount of myocardium at risk in patients with an acute myocardial infarct and to assess myocardial salvage

following percutaneous transluminal coronary angioplasty and/or thrombolysis. In these acute situations, the 10-13-sec microwave oven heating method (2-4) does provide a fast and cost-effective preparation method for emergency use of ^{99m}Tc-sestamibi without the need for advance preparation of multiple kits each day. Although ^{99m}Tc-sestamibi vial breakage has been reported during the microwave heating process (5), the improved cushioned packaging with a foam insert in each Cardiolite kit (6) seems to help solve the problem of vial breakage attributed to pre-existing microscopic impact flaws on the glass vial. If one is still concerned about the potential for vial breakage during the microwave heating procedure, an alternative method for the rapid preparation of ^{99m}Tc-sestamibi has been developed in our laboratory (7). Technetium-99m-sestamibi can be quickly prepared with a 2-min incubation in an insulated beaker filled with hot water from an instant hot water machine (7). As with the other preparation methods (e.g., boiling water bath, heating block and microwave oven heating methods), the instant hot water method would also have a higher hand exposure to the operator when compared to the Recon-o-Stat method (1). It would be interesting to see the comparison of hand exposure between the Recon-o-Stat method and the other non-microwave heating methods (i.e., the standard boiling water bath method (8) and the other two alternative methods: heating block and instant hot water methods).

Heating Temperature versus Radiochemical Purity

As shown in the study by Porter and Karvelis, the immediate and 24-hr radiochemical purity (RCP) values of ^{99m}Tc-sestamibi prepared by the Recon-o-Stat method were significantly lower than the microwave RCP values (1). Some of the 24-hr Recon-o-Stat RCP values were below the recommended 90% acceptance limit (8), whereas all of the measured 24-hr microwave RCP values maintained at an average of $97.3 \pm 1.1\%$ (1). Since ^{99m}Tc-sestamibi can be used within 6 hr post-preparation (8), it is essential to determine whether the Recon-o-

Stat ^{99m}Tc-sestamibi preparation that has a borderline immediate RCP value (i.e., 90-92%) will sustain a passing RCP value (i.e., $\geq 90\%$) throughout the entire 6-hr shelf life. As stated in the package insert for Cardiolite (8), ^{99m}Tc-sestamibi preparation with an RCP value of at least 90% has been proven to be safe and effective in the previous clinical trial. Nevertheless, one should always try to provide patients with the radiopharmaceutical that has the highest achievable RCP value in order to minimize the amount of undesirable radiochemical impurities to the patient. This would not only reduce unnecessary radiation exposure to the patient, but would also decrease any interference with image interpretation caused by radioactive impurities. Both the recommended boiling water bath method (8) and the microwave oven heating method (2-4) consistently produce the highest ^{99m}Tc-sestamibi RCP value (1-4).

Although the package insert for Cardiolite does not contain any specific restrictions with regard to the use of a first eluate from a long ingrowth-time generator (i.e., Monday generator) to reconstitute the kit (8), one Recon-o-Stat kit prepared with such an eluate resulted in an RCP value of 82.5% (1). In the comparison study by Porter and Karvelis (1), a substantially higher amount of ^{99m}Tc activity was used in the reconstitution of the Cardiolite kit (i.e., 22.2 GBq, 600 mCi versus the standard 5.55 GBq, 150 mCi (8)). A similar observation was noted in our previous report (9). We have found that the use of old (i.e., >6 hr post-elution) eluate from a long-ingrowth generator in the preparation of a ^{99m}Tc-sestamibi kit is associated with a high rate of kit failure (i.e., RCP value <90%). Higher failure rates of the ^{99m}Tc-sestamibi kit are noted especially when higher activities of ^{99m}Tc eluate are used to reconstitute the Cardiolite kit (9).

According to the specifications for the Recon-o-Stat thermal controller (10), the thermal range of this Peltier heat pump is 0-119°C with a programmed target temperature set at $119 \pm 0.7^\circ\text{C}$. This temperature is clearly much higher than the water temperature in the boiling water