Radioiodine Volatilization from Reformulated Sodium Iodide I-131 Oral Solution

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By changing the pH and adding buffers, antioxidants, and stabilizers to a sodium iodide (I-131) oral solution, a reduced radioiodine volatilization was claimed by a commercial supplier of radiopharmaceuticals. This study compares the airborne radioactivity volatilized from the reformulated sodium iodide solution with that which became airborne from a previous formulation. Air samples were obtained from the fume hood's exhaust stack during initial venting, and from the breathing zones of physicians and technologists administering the solution to the patient. Analysis of the air samples indicates significant reduction in the airborne radioiodine following initial venting of the solution vial and during patient administration. Additionally, there has been a decline in the I-131 thyroid burdens for occupationally exposed personnel handling the reformulated sodium iodide solutions.

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A recent report by the US Nuclear Regulatory Commission indicated that significant quantities of radioactive iodine-131 may be released to the atmosphere through iodine volatilization when the vial cap on a therapeutic dose is opened (*1*). This announcement led several investigators to report their concern over airborne concentrations of I-131 during therapy procedures (*2–4*). In response to this concern, our supplier of sodium iodide (I-131) oral solution announced a reformulation of its product to reduce I-131 volatilization (*5*). The purpose of the present study was to measure airborne concentrations of iodine-131 from millicurie quantities of reformulated oral solution and to compare them with airborne concentrations measured from the solution as originally formulated.

MATERIALS AND METHODS

Iodine-131 is routinely received at our facility, in high-concentration sodium iodide aqueous solutions (25–35 mCi/ml), for oral administration to patients for thyroid cancer treatments. Until recently, the manufacturer's* product label and package insert identified the oral solution as meeting the standards of the US Pharmaecopia, except that the solution pH was in the range 2.0–4.0, rather than the specified 7.5–9.0 range. Then in April 1979 we received a letter (*5*) from our supplier announcing a reformulation of the sodium iodide (I-131) oral solution to reduce the volatilization and resulting unnecessary personnel exposure to I-131, and stating in part:

> The new formulation includes sodium bisulfite which is an antioxidant. It minimizes chemical- and radiation-induced changes in the iodide ion which could result in the formation of volatile free iodide. Disodium phosphate buffers the solution which keeps the pH in the 7.5–9.0 range. This is the range specified in the current U.S.P. And, disodium edetate has been added as a stabilizer.

In an attempt to confirm the manufacturer's claim of reduced volatility, representative air samples were taken at various stages during the routine manipulation of the vial of iodine-131 solution. After we receive and unpack the material, our normal handling procedure for iodine-131 oral solution is to store the vial unopened in a fume exhaust hood. Initial venting of the vial is postponed until just before administration, when the vial is uncapped and vented 5–7 min in the hood while the airflow carries any airborne iodine-131 to the exhaust vent on the roof. The vial is then recapped, its activity measured in the dose calibrator, and it is then transported to the ward for administration to the patient. At the ward, the vial is placed at bedside and opened by a nuclear medicine technologist. While the patient sucks the material through a straw, the administering physician adds water to the vial to ensure maximum ingestion of the radioactive material by the patient.

This typical dose routine suggested two areas of concern for personnel exposure to airborne iodine-131, during initial venting and during dose administration, since the vial is capped at all other times. Air samples were collected from the rooftop vent of the exhaust hood during the vial venting of the oral solution. Additional air samples were obtained in the breathing zone of the administering physician and the assisting technologist at the time the iodine-131 was administered to the patient.

Air samples were obtained using a regulated, constant-flow air sampler† for personnel monitoring, drawing a calibrated 2.0 l/min

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through a charcoal sampling tube‡. This flow rate was chosen to allow collection of a representative air sample that would not unduly perturb the normal air patterns, but would still allow sufficient sensitivity to iodine-131 during reasonable collection and analysis times. The battery-powered pump is clipped onto the belt, is compensated to pump at a constant rate should the filter become clogged, and is connected to the sampling tube by flexible plastic tubing

The sampling tube was hand-held for the rooftop vent measurement but was attached to the physician's or technologist's collar during administration to the patient, to enable collection of air from the individual's breathing zone. Air samples were collected for periods of 2–7 min, monitoring continuously the entire time that the iodine-131 solution vial was open. Each sampling tube contained two charcoal beds, 600 mg total, separated by a section of fiberglass wool. After the sample collection, the tube was crushed so that the charcoal beds could be placed in separate counting tubes and analyzed on a crystal scintillation well counter.

Since the two charcoal beds in the sampling tube were in series, the collection efficiency for iodine-131 could be monitored for each filter. The absense of radioactivity in the rear charcoal bed indicated that the iodine-131 had been completely trapped in the front charcoal bed. Sample counting times ranged from 1–4 min, which, in conjunction with the sample collection time (volume) and the detection efficiency of the analyzer, allowed a minimum detectable activity statistically significant above the background fluctuations of 2.0×10^{-9} μCi/ml.

Thyroid burdens of iodine-131 for occupationally exposed personnel were determined by using a thyroid uptake probe. The individual's thyroid was counted at 25 cm from a 5-cm sodium iodide crystal for a 3-min interval. The uncertainty in the radioactive standard and the detection efficiency of the analyzer, combined with the statistical fluctuation of the background and thyroid activities, produced an average minimum detectable activity of 0.025 μCi iodine-131 in the individual's thyroid.

RESULTS

The airborne concentrations of iodine-131, measured from vials containing 80–176 mCi at the time of initial venting, are presented in Tables 1 and 2. Shown in Table 1 are the airborne concentrations resulting from the vials of reformulated sodium iodide, while Table 2 presents those resulting from the original formulation. The indicated uncertainty in the concentrations is the 2σ or 95% confidence level and is a combination of uncertainties in the measured activity, the sample volume, and the detection efficiency of the analyzer. Summaries of iodine-131 thyroid burdens for personnel handling the different solution formulations are given in Table 3.

TABLE 1. AIRBORNE CONCENTRATION OF I-131 FROM REFORMULATED SODIUM IODIDE SOLUTION

Activity of liquid in vial at venting (mCi)	Rooftop vent exhaust (10^{-9} μCi/ml)	Physician's breathing zone (10^{-9} μCi/ml)	Technologist's breathing zone (10^{-9} μCi/ml)
105	3.9 ± 1.2	≤2.0	≤2.0
95	1.84 ± 1.0	16.2 ± 4.9	2.5 ± 2.0
137	27.4 ± 4.2	*	23.1 ± 3.0
109	17.2 ± 2.4	*	159 ± 28

* Not monitored.

TABLE 2. AIRBORNE CONCENTRATION OF I-131 FROM ORIGINAL SODIUM IODIDE FORMULATION

Activity of liquid in vial at venting (mCi)	Rooftop vent exhaust (10^{-9} μCi/ml)	Physician's breathing zone (10^{-9} μCi/ml)	Technologist's breathing zone (10^{-9} μCi/ml)
80	715 ± 60	840 ± 75	*
176	1380 ± 240	1980 ± 215	*
103	1250 ± 220	4800 ± 500	15000 ± 1560
119	760 ± 130	*	*
109	240 ± 25	6200 ± 650	360 ± 40

* Not monitored.

DISCUSSION

Comparison of the data in Tables 1 and 2 indicates a significant reduction in the amount of airborne iodine-131 from the venting of the reformulated solution of sodium iodide, compared with the original solution formula. The concentration of iodine-131 leaving the stack was reduced from $240–1380 \times 10^{-9}$ μCi/ml to $1.8–27.4 \times 10^{-9}$ μCi/ml, which reduces considerably the environmental pollution and the volume of air necessary to dilute the pollutant concentration to the legal average of 0.1×10^{-9} μCi/ml required by the US Nuclear Regulatory Commission (*6*).

Even more pronounced was the reduction of airborne iodine-131 concentration measured in the breathing zone of personnel administering the solution to the patient. The measured concentrations were reduced from $360–15{,}000 \times 10^{-9}$ μCi/ml to $\leq 2.0–159 \times 10^{-9}$ μCi/ml, which is much closer to the legal average concentration for continuous exposure (9×10^{-9} μCi/ml) required by the US Nuclear Regulatory Commission (*6*). The large airborne concentrations from the original formulation required that restrictions be placed on personnel, such that individuals could participate in only one sodium iodide therapeutic procedure for 3 min every 2 wk, in order to maintain their exposure below the quarterly average concentration for continuous exposure. For this reason a roster of exposed personnel was established and the duties were rotated to preclude any one individual from being exposed to integrated concentrations of radioiodine that would exceed the

TABLE 3. THYROID BURDENS OF PERSONNEL HANDLING SODIUM IODIDE THERAPEUTIC SOLUTIONS

Type of solution formulation	Occupationally exposed individuals	Individual thyroid counts performed	Individual thyroid burden >0.025 μCi
Original	15	75	9
Reformulated	12	34	0

equivalent of continuous exposure at the maximum permissible concentration.

With the reduced airborne concentrations produced from the reformulated sodium iodide, an individual could theoretically participate in one 3-min procedure per hour and still not exceed the maximum permissible exposure. To be quite safe, however, we are still maintaining the rotating duty roster.

The effect of reformulation of the sodium iodide on the measured thyroid burdens has also been noticed. Since our change to the reformulated solution, none of the 34 thyroid measurements on occupational personnel has been positive (greater than 0.025 μCi) whereas with the original formulation nine of 75 thyroid measurements (12%) were above this minimum detectable activity. The reduced incidence of positive findings obviously indicates a reduction of the potentially hazardous consequences of working with this material.

CONCLUSIONS

The "reformulation" of iodine-131 sodium iodide oral solution by our supplier has significantly reduced the volatilization of radioiodine into the air during initial venting of the solution vial. Also reduced is the volatilization of radioiodine during administration of the dose to the patient. This reduction of radioiodine in the air has led to less environmental contamination, less hazard potential to occupationally exposed personnel, and fewer actual uptakes of iodine-131 among personnel handling the vials of reformulated sodium iodide solution.

FOOTNOTES

* Mallinckrodt, Inc., St. Louis, MO.

† Model P4000A, E. I. Dupont de Nemours & Co., Inc., Wilmington, DE.

‡ Catalog No. 226-09, SKC Inc., Eighty Four, PA.

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