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Absorbed Radiation Doses to Staff After Implementation of a Radiopharmacy Clean Room

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In response to U.S. Pharmacopeia general chapter <797> standards, a clean room was constructed for our in-house radiopharmacy. Previously, most patient doses were prepared as needed just before injection. Currently, to minimize repeated entries into the clean room, most patient doses are prepared in batches; that is, early morning and noontime preparation of doses to be injected at various times throughout the morning and the afternoon, respectively. Because these patient doses may be prepared well before injection time, radioactive decay necessitates higher amounts of radioactivity to be handled for patient dose preparation. Hence, absorbed radiation doses to staff, all of whom rotate into the radiopharmacy clean room in addition to their regular patient-related activities, were retrospectively evaluated. **Methods:** Monthly dosimetry reports for body (chest badge) and extremities (finger ring) were retrospectively reviewed for each staff member for 12 mo before and 12 mo after implementation of the radiopharmacy clean room. Monthly data were evaluated for average and SD, and 12-mo groups were evaluated using a paired *t* test. Data for the second 12-mo period were also normalized to the same number of patient doses to account for an increase in procedure volume and were reevaluated. **Results:** Before the radiopharmacy clean room had been implemented, average monthly absorbed radiation doses to body and extremities were 23 ± 15 mrem (0.23 ± 0.15 mSv) and 93 ± 59 mrem (0.93 ± 0.59 mSv), respectively. After the clean room had been implemented, average monthly absorbed radiation doses increased to 32 ± 16 mrem (0.32 ± 0.16 mSv) ($P < 0.001$) and 121 ± 89 mrem (1.21 ± 0.89 mSv) ($P = 0.0015$), respectively. When normalized for procedure volume, average monthly absorbed radiation doses after implementation of the clean room were still higher, at 29 ± 15 mrem (0.29 ± 0.15 mSv) ($P = 0.001$) and 110 ± 80 mrem (1.10 ± 0.80 mSv) ($P = 0.039$), respectively. **Conclusion:** After implementation of a radiopharmacy clean room, absorbed radiation doses to body and extremities increased by 26% and 18%, respectively, even after normalizing for procedure volume. Because absorbed radiation doses from other activities, such as patient dose administration and patient imaging, are assumed to remain relatively constant, these increases in absorbed radiation doses to staff are attributed to changes in work flow after implementation of the radiopharmacy clean room.

Key Words: radiation absorbed dose; radiopharmacy; clean room

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Our institution has an in-house radiopharmacy lab, where ^{99}Mo generators are eluted, reagent kits are radiolabeled, and patient doses are prepared. Traditionally, most patient doses were prepared (i.e., drawn up into a syringe) by staff technologists as needed just before injection. In response to the U.S. Pharmacopeia general chapter <797> standards (*1*), our radiopharmacy lab was renovated to incorporate the applicable environmental conditions for compounding sterile preparations; that is, an International Organization for Standardization class 5 hood in a class 7 clean room with an adjacent class 8 anteroom. Entry into the clean room involves prerequisite hand cleansing and donning of shoe covers, a hair cover, a face mask, a gown, and gloves, a process that takes many minutes and incurs a cost of several dollars for disposable garb. To minimize repeated entries into the clean room, and thus the associated time and cost, most patient doses since implementation of the radiopharmacy clean room are prepared in batches; that is, early morning preparation of patient doses scheduled to be administered at various times throughout the morning, and noontime preparation of patient doses scheduled to be administered at various times throughout the afternoon. Because most of these patient doses are precalibrated for a future time, higher amounts of radioactivity are necessarily handled at the time of preparation to allow for radioactive decay. Hence, absorbed radiation doses to staff technologists who rotate into the radiopharmacy clean room are presumably higher after implementation of the radiopharmacy clean room than they were previously. The objective of this study was to retrospectively evaluate absorbed radiation doses to staff technologists before and after implementation of our radiopharmacy clean room.

MATERIALS AND METHODS

Anonymized monthly dosimeter reports for body (chest badge) and extremities (finger ring) were retrospectively reviewed for each staff technologist ($n = 12$) for the 12-mo period immediately

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TABLE 1
Summed Monthly Radiation Doses to the 12 Staff Technologists Before and After Implementation of Radiopharmacy Clean Room

Month	Before			After		
	Body	Extremities	Doses (*n*)	Body	Extremities	Doses (*n*)
July	185 (1.85)	870 (8.70)	604	267 (2.67)	1,090 (10.90)	546
August	250 (2.50)	1,210 (12.10)	623	403 (4.03)	1,510 (15.10)	700
September	309 (3.09)	1,240 (12.40)	694	362 (3.62)	1,630 (16.30)	751
October	261 (2.61)	1,050 (10.50)	613	413 (4.13)	1,720 (17.20)	703
November	314 (3.14)	1,330 (13.30)	607	318 (3.18)	1,300 (13.00)	718
December	249 (2.49)	1,040 (10.40)	603	439 (4.39)	1,110 (11.10)	605
January	236 (2.36)	1,020 (10.20)	608	417 (4.17)	1,540 (15.40)	728
February	317 (3.17)	1,230 (12.30)	627	433 (4.33)	1,680 (16.80)	737
March	317 (3.17)	1,240 (12.40)	701	426 (4.26)	1,700 (17.00)	846
April	314 (3.14)	880 (8.80)	672	387 (6.87)	1,420 (14.20)	715
May	250 (2.50)	1,070 (10.70)	647	375 (3.75)	1,520 (15.20)	729
June	317 (3.17)	1,190 (11.90)	655	322 (3.22)	1,260 (12.60)	654
Total	3,319 (33.19)	13,370 (133.70)	7,654	4,562 (45.62)	17,480 (174.80)	8,432

Data are mrem followed by mSv in parentheses.

before and the 12-mo period immediately after implementation of the radiopharmacy clean room. Individuals' absorbed radiation doses were summed for each month, and these summed data were evaluated for average and SD. Absorbed radiation doses for each of the 12-mo periods were evaluated for significant difference (i.e., $P < 0.05$) using a paired *t* test. Because of an increase in procedure volume, data for the second 12-mo period were also normalized for number of patient doses and reevaluated.

RESULTS

Data on summed absorbed radiation doses to staff technologists are presented in Table 1. The results of the evaluation of these absorbed radiation doses are presented in Table 2. Before implementation of the radiopharmacy clean room, average monthly absorbed radiation doses to body and extremities were 23 ± 15 mrem (0.23 ± 0.15 mSv) and 93 ± 59 mrem (0.93 ± 0.59 mSv), respectively. After implementation of the radiopharmacy clean room, average monthly absorbed radiation doses increased to 32 ± 16 mrem (0.32 ± 0.16 mSv) ($P < 0.001$) and 121 ± 89 mrem (1.21 ± 0.89 mSv) ($P = 0.0015$), respectively. When normalized on the basis of the ratio of the number of patient doses for the 12-mo periods (i.e., 7,654 doses/8,432 doses), average monthly absorbed radiation doses to body and extremities after implementation of the radiopharmacy clean room were still higher, at 29 ± 15 mrem (0.29 ± 0.15 mSv) ($P = 0.001$) and 110 ± 80 mrem (1.10 ± 0.80 mSv) ($P = 0.039$), respectively.

DISCUSSION

In our institution, staff technologists rotate through the radiopharmacy clean room, where they prepare patient doses, in addition to their traditional activities such as administering radiopharmaceuticals to patients and performing patient imaging procedures. Hence, only a fraction of their total absorbed radiation doses are from patient dose preparation in the radiopharmacy clean room. Because absorbed

TABLE 2
Average Monthly Radiation Doses to the 12 Staff Technologists Before and After Implementation of Radiopharmacy Clean Room

Interval	Body		Extremities	
	Dose	*P**	Dose	*P**
Before	23 ± 15 (0.23 ± 0.15)		93 ± 59 (0.93 ± 0.59)	
After	32 ± 16 (0.32 ± 0.16)	<0.001	121 ± 89 (1.21 ± 0.89)	0.0015
After, normalized for no. of patient doses	29 ± 15 (0.29 ± 0.15)	0.001	110 ± 80 (1.10 ± 0.80)	0.039

*Paired *t* test.
Data are mean mrem ± SD followed by mSv in parentheses.

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radiation doses from their traditional activities are assumed to remain relatively constant, the increase in absorbed radiation doses after implementation of the radiopharmacy clean room can be attributed to changes in workflow, that is, handling higher amounts of radioactivity to prepare precalibrated patient doses.

Because there was an increase in procedure volume after clean room implementation, absorbed radiation doses for the second 12-mo period were normalized on the basis of the ratio of the numbers of patient doses from the 12-mo periods (i.e., 7,654 doses/8,432 doses). This simple normalization did not take into account any possible differences in procedure mix (e.g., type of procedure, adult vs. pediatric doses, or time of day). Normalization by procedure mix was beyond the scope of this study. However, any differences in procedure mix were judged to be minor and their influence on these analyses to be inconsequential.

CONCLUSION

After implementation of a radiopharmacy clean room, and the associated change in workflow, absorbed radiation doses to body and extremities of staff technologists increased significantly (by 26% and 18%, respectively). However, such absorbed radiation doses remained well below regulatory limits, and the increased radiation risks are judged to be outweighed by the increased benefits (i.e., safety assurance) of aseptic patient dose preparation.

DISCLOSURE

No potential conflict of interest relevant to this article was reported.

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