VOID SHEET

TO: License Fee Management Brance FROM: R.J.	
SUBJECT: VOIDED APPLICATION	
Control Number: 255603	The
Applicant: Merity Hea	ITA UGS.
Date Voided: 3/9/94	
Reason for Void: All apple telecon fivilie d alfund fec.	eant lone - de not
refund fec.	
	Signature Date
Attachment: Utficial Record Copy of Yoided Action	
FOR LEMB USE ONLY	73
Final Review of VUID Completed:	
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Befund Authorized and processed	£N : 42
No Refund Due	2
Fee Exempt or Fee Not Required	
Comments:	Log completed Born 3/14/94
403240026 940309 DR ADOCK 03032701 PDR	Processed by: <u>Born 3/14/94</u> ML201

144 9 492

Meritus Health Systems, Inc. ATTN: Mr. Martin Hellcamp 233 Hershberger Road, Suite 200 Roanoke, Virginia 24012

Gentlemen:

SUBJECT: ABANDONMENT OF AMENDMENT REQUEST (REFERENCE: CONTROL NO. 255603; DOCKET NO. 030-32701)

In a letter dated October 5, 1993, Meritus Health Systems requested the addition of authorized users onto License No. 45-25194-01. In telephone conversations with the physicians' organization, we learned that the action had been filed prematurely. In further conversations between the physicians' group, and Meritus Health Systems, Inc. it was apparently decided that the amendment request be abandoned. In a telephone conversation between Mr. Martin Hellcamp and Mr. D. Collins on February 16, 1994, Meritus Health Systems, Inc. requested that the action requested in the October 5, 1993 letter be withdrawn. Since no written request has been received since February 16, 1994, we consider the October 5, 1993 amendment request to be abandoned based upon that telephone conversation.

The current version of License No. 45-25194-01 is Amendment 2, dated May 3, 1993. If your understanding of this matter is different, please contact me at (404) 331-5624, or facsimile (404) 331-5559. Your cooperation is appreciated.

Sincerely,

DIPIGINAL SIGNED BY

David J. Collins Health Physicist Nuclear Materials Licensing Section NMSS

Enclosure: Amendment No. 2, License No. 45-25194-01

bcc: Reading File

RLI: DRSS DaCollins. 3/8/94

TIME DATE CONVERSATION RECORD TYPE ROUTING VISIT CONFERENCE TELEPHONE NAME/SYMBOL INT INCOMING Location of Visit/Conference: OUTGOING NAME OF PERSON(S) CONTACTED OR IN CONTACT ORGANIZATION (Office, dept., buresu, TELEPHONE NO. WITH YOU ete.) 22 xM 700 SUBJECT SUMMARY (at as portal. in Trancio Continue A. Avrmort anunlmen leamp says not 1Aug tix printe ACTION REQUIRED amendment 3 dated 10/5/23 application 21 3.1 NAME OF PERSON DOCUMENTING CONVERSATION SIGNATURE DATE 0 ACTION TAKEN SIGNATURE TITLE DATE 50271-101 OFTIONAL FORM 271 (12-76) DEPARTMENT OF DEFENSE + U.S.QPO 1990-202-081/20175 CONVERSATION RECORD

OCT 2 9 1993

703 563-8700

Meritus Health Systems, Inc. ATTN: Paul Logan 233 Hershberger Koad Roanoke, VA 24012

Gentlemen:

This refers to your letter dated October 5, 1993, for an amendment to Materials License 45-25194-01.

Your request is subject to an amendment fee of \$500 as specified in fee Category 7C of 10 CFR 170.31 of the enclosed July 20, 1993, <u>Federal Register</u> notice. Payment of the \$500 fee should be made to the U.S. Nuclear Regulatory Commission and mailed to the following address:

> U.S. Nuclear Regulatory Commission ATTN: Rita Messier License Fee and Debt Collection Branch, OC/DAF Mail Stop MNBB 4503 Washington, D.C. 20555

Your application will be processed by the Region II Licensing staff located at 101 Marietta Street, Suite 2900, Atlanta, GA 30323. The fee, however, is required prior to issuance of the amendment. When submitting the fee, please refer to CONTROL NUMBER 255603.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application and will void this action.

Sincerely,

Rita Messier License Fee and Debt Collection Branch Division of Accounting and Finance Office of the Controller

Enclosure: July 20, 1993, <u>Federal Register</u> notice

cc: Region II

DISTRIBUTION Pending Fee File OC/DAF R/F LFDCB R/F (2)

OFFICE: OC/LFDCB OC/LFDCB NAME: RMessier SKimberley DATE: /0 1281 93 0129193

AB/A:\MHS.ANC

(FOR LEMS USES INFORMATION FROM LTS BEIWEEN: LICENSE FEE MANAGEMENT ARANCH, ARM : PROGRAM CODE: 02220 : STATUS CODE: 0 . REGIONAL LICENSING SECTIONS : FEE CALEGORY: 7C.28. : EXP. DATE: 19970831 FOE COMMENTS: 1 DECOM AIN ASSUR REQUI N LICENSE FEE TRANSMITTAL A. REGIONIL 1. APPLICATION ATTACHED APPLICANT/LICENSEE: MERITUS HEALTH SYSTEMS, INC. RECEIVED DATE: 931012 OOCKET NO: 3032701 CONTROL NO.: 255603 PRIORITY LICENSE NO.1 45-25194+01 ACTION TYPE: AMENDMENT 2. PEE ATTACHED AMOUNT: CHECK NO.1 3. COMMENTS. DATE Change de Kleine PER CATEGORY AND AMOUNT: (7528 B 1 . CORRECT PEE PAID . APPLICATION MAY SE PROCESSED FOR: 2 . AMENDMENT RENEWAL LICENSE 3. UTHER SIGNED Rila Messer 1863 OCL 52 BN 3: 56

MERITUS HEALTH SYSTEMS, INC.

233 Hershberger Road Roanoke, VA 24912, (703) 563-8700

October 5, 1993

Mr. David Collins Health Physicist Nuclear Materials Safety Section USNRC 101 Marietta St. NW Atlanta Georgia 30323

Mr. Collins,

Hello! I hope things are going well.

Meritus Health Systems would like to ammend their Radioactive Materials license (45-25194-01) by adding the following authorized users all of which are listed on Herbert J. Thomas Memorial Hospitals license (# 47-17746-01) and authorized for Medical uses as described in CFR 35.100, 35.200, 35.300.

David Abramowitz MD W. Alva Deardorff MD Ravindra Gogineni MD Thomas M. Hayes MD Martin S. Wershba MD George B. Wilson MD Pratima Saldanha MD Carl B. Binns MD Nicholas Cassis Jr. MD Mohammed Babar Yousaf MD

I had an article Published in the Journal. Thought you might like some light reading!

Please let me know if there is any additional information you need.

Respectfully,

Paul Loaan

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RADIATION SAFETY

Differential Syringe Shield Effectiveness: Direct Comparisons Using SPECT and Planar Imaging

Paul Logan

Department of Nuclear Medicine, Meritus Health Systems, Roanoke, Virginia

The use of syringe shields in clinical nuclear medicine has been employed to reduce occupational exposure. However, there is little, current, comparative literature available for the diverse number of products available. I performed single-photon emission computed iomography (SPECT) acquisition on four different shields, and the results were quantitated in order to evaluate the percentage of counts relative to an unshielded source and to the other models tested. All models tested were found to significantly reduce available counts, with the thin-wall shield producing the highest number of counts at the viewing port and the tungsten shield being the least effective overall. I concluded that the intrinsic differences between model design and materials utilized determines the overall efficiency, and that this information is important in light of both the as low as reasonably achievable (ALARA) principle and biological model concepts.

J Nucl Med Technol 1993; 21:167-170

The formal adoption of the as low as reasonably achievable (ALARA) principle (I, 2) in clinical nuclear medicine and the advocation of syringe shield use has reduced occupational exposure (3) during the many facets of radiopharmaceutical preparation and administration. When use of syringe shields has been widespread, the shields have reduced such exposure (4, 5). However, consistent usage of these shields has been low, despite the consensus among technologists that they are effective (6). A recent literature search by the author concluded that there are few current studies available on syringe shield effectiveness. In addition, there is no detailed information available, which directly compares the new products now being marketed. I have tested four models to determine individual absolute effectiveness and relative effectiveness.

MATERIALS AND METHODS

The following 3-ce syringe shields were compared for shielding effectiveness: Gamma Vue Model 56-262 (Nuclear

For reprints contact: Paul Logan, CNMT, Medical Diagnostic Imaging, 805 Hackory Woods, Dr. #88, Roanoke, VA 24012.

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Associates, Carle Place, NY), which incorporates a lead barrel and a high density lead-glass viewport; All Vue Model 56-212 (Nuclear Associates), which incorporates a 50% lead barrel and 50% high density lead-glass viewport; Pro-Tee II Model 007-800 (Biodex Medical Systems, Shirley, NY), which incorporates a tungsten alloy barrel and a high density lead-glass viewport; and Thinwall Shield Model 56-272 (Nuclear Associates), which incorporates a lead barrel and a lead-glass viewport.

Four doses of technetium-99m-pertechnetate ($^{99m}TeO_4^-$) were drawn in 3-ec syringes, each containing 20.2 mCi in a total volume of 1.2 cc/dose. Each dose was assayed using a Capintee 15R dose calibrator (Capintee, Ramsey, NJ), which was tested for accuracy and constancy prior to the study and found to be within normal limits. Each needle was removed and all doses reassayed to insure the integrity of the activity attained. The remaining air was expelled up to the needle hub base and individual syringes were secured in one of the four shields so as not to extend any portion of the dose beyond the shield nose. All doses were then arranged on the imaging table in the spatial configuration illustrated in Figure 1.

Images were then acquired using a Summit Nuclear 1024R gamma camera (Summit Nuclear Systems, Twinsburg, OH).

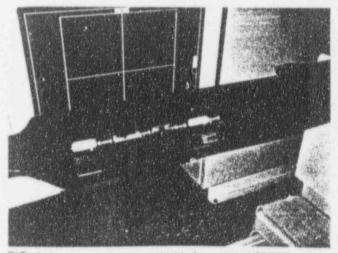


FIG. 1. Placement of syringe shields for a trial of SPECT acquisitions

TABLE 1. Statistical Profile of Total and Mean Counts Detected from a 1024 × 1024 pixel ROI in a 360° SPECT Acquisition

Shield Type	Total Counts/Pixel		Mean Counts/Pixel				
	τ.	% Shielded	S,	% Shielded (A _x)	Max. Counts Pixel	Standard Deviation	Variance
Gamma Vue All Vue Pro-Tec II Thinwail Unshielded	48006 112049 346537 309008 7905656	99-39 98-58 95-62 96-10 N/A	46 109 338 301 11694	99.61 99.10 97.11 97.43 N/A	1130 1774 7001 10448 152911	130 271 972 1221 28507	16900 73441 944784 1490841 812649049

which had been checked for uniformity and linearity and undergone a center of rotation (COR) determination. The camera was outfitted with a low energy general purpose collimator and rotated to -180° . Three clockwise circular orbit SPECT acquisitions were then obtained using a 128 × 128 matrix, a symmetric photopeak centered at 140 keV with a 20% window, and no magnification liext, 64 frames were acquired at 5 sec/stop with the collimator face 21 cm from the rotational center. These acquisition parameters were repeated and 64 frames were acquired with an unshielded syringe containing 20.2 mCi of pertechnetate in a total volume of 1.2 cc.

Planar images were also acquired using the same syringe and computer parameters. Individual syringes were placed on the low energy general purpose collimator and 5-sec acquisitions were obtained. Each syringe was rotated -180° , hiding the viewport from the detector head, and the acquisition was repeated.

RESULTS

The absolute effectiveness (Ax) is given by the formula:

$$A_x = \frac{U_1}{S_x}\,,$$

where S_x is the shielded mean counts and U₁ is the unshielded mean counts detected in a 1024 × 1024-pixel region of interest (ROI). The calculated effectiveness for each syringe is shown in Table 1.

The relative effectiveness (R_x) is given by the formula:

$$R_x = \frac{T_{max}}{T_x},$$

where T_{max} is the highest number of counts detected and T_x is the total counts detected in the 1024-pixel ROI. The calculated relative effectiveness for each of the shields is shown in Table 2.

In addition to the quantitative assessments made, qualitative activity curves were generated for Frames 1 through 64. A 1024×1024 pixel ROI was drawn for each syringe on a

summed image of all 64 frames. These curves are illustrated in Figure 2. At Frame 1, the detector was positioned at -180° ; the position exposing no viewport. At Frame 32, the detector was positioned at 0°, facing the viewport of each syringe. Planar acquisitions yielded the number of counts with the collimator facing each viewport (0°) and at -180° . These values are shown in Table 3.

DISCUSSION

The SPECT data in Table 2 support the conclusion that the Gamma-Vue shield is, overall, the most effective model tested. The All-Vue shield is the second most effective, while the Thinwall shield and the Pro-Tee II are third and fourth, respectively. The planar data in Table 3 validate this conclusion with the noted exception that the Gamma Vue displayed a slightly higher than expected count at -180° .

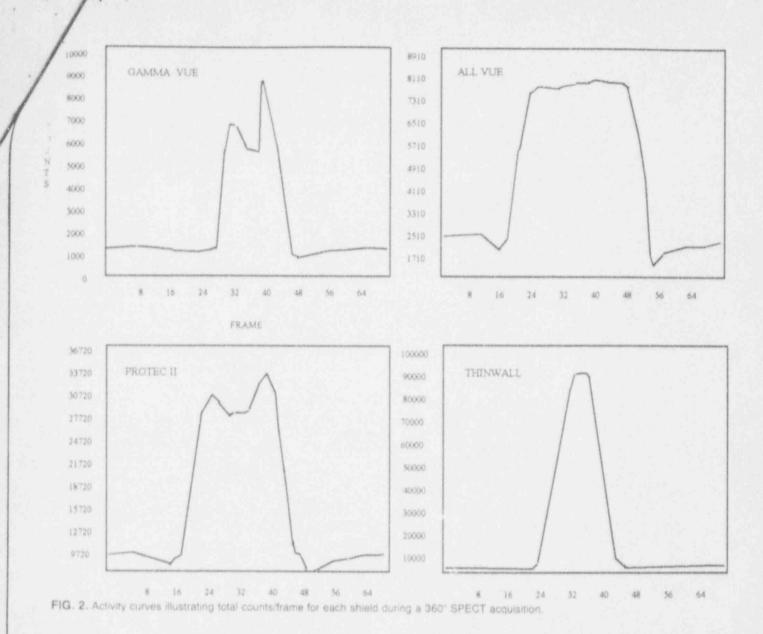
Much information can be gleaned from the distribution of counts found in the activity curves (Fig. 2). Note the dual peaks detected at Frames 30 and 37 for the Gamma-Vue and at Frames 26 and 40 for the Pro-Tec II. Upon examining both models, I determined that these peaks were due to the lack of shielding that was found when the detector head was facing the angles displayed in Figure 3. In contrast, the Thinwall shield exhibited a single peak of activity. Also note in Figure 2 the more uniform distribution of activity for the All-Vue, which can be attributed to a more uniform shield design. These cross sections are depicted in Figure 4.

It follows that greater exposure will occur near the viewing port where visibility and shielding are inversely related. However, exposure still occurs around the circumference of the shield, the amount detected being a function of thickness

TABLE 2. Relative Effectiveness for Each Syringe Using Total Counts

Shield Type	Relative Effectiveness
Gamma Vue All Vue Pro-Tec II	7.21 3.09 1.00
Thinwall	1.12

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and choice of materials. A detailed analysis of the activity curves in Figure 2 reveals the differential levels of activity along the circumference of each syringe. Also note the signal attenuation that occurs at roughly Frames 8 through 20 and 46 through 58 for each shield, as a result of the imaging couch being in a direct line between the sources and the detector.

As indicated in Figure 2 and the planar data in Table 3, the Thinwall shield exhibited the highest number of viewport

> TABLE 3. Counts Detected from Planar Acquisition of Each Syringe Shield at 0° and 180°

	Total Counts		Max./Pixel	
Shield Type	-180°	0.	- 180°	0"
Gamma Vue	123123	15152	2513	2612
All Vue	9004	17367	2251	2730
Pro-Tec II	15704	34543	2293	2414
Thinwall	11697	99469	2941	9279

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counts at Frame 32. This was due to the relatively thin glass used during construction as well as the larger viewing surface (see Fig. 4). The Tungsten Pro-Tec II displayed less

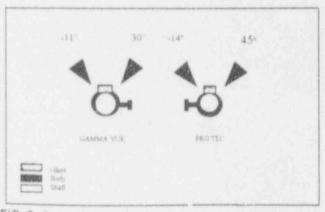


FIG. 3. Gamma Vue and Pro-Tec II snield cross sections revealing areas of thin shielding (indicated by the arrows) and their corresponding detector angles, which detected higher counts

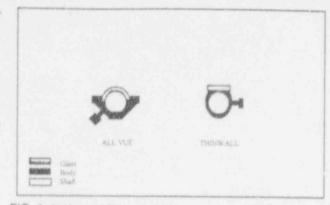


FIG. 4. All Vue and Thinwall shield cross sections denoting uniform shielding design.

viewport activity than the Thinwall shield; however, it had the highest number of counts detected along the remaining circumference.

CONCLUSION

Since this study was a pilot study, the conclusions drawn are only pertinent to the models tested and I acknowledge the need for further experimentation encompassing other models (e.g., Viox model 320, 3-cc, 360°, lead glass, cylindrical body, Viox Corporation, Scattle, WA). In addition, other variables such as differential activities, isotopes, and volumes need assessment.

While a survey by Burr (5) indicated that the fungsten and thinwall designs are the most frequently used, my study has

determined that these designs are the least effective. The Burr study cited bulk, fragility, and cost as determinants in shield selection. Certainly other factors such as injection facilitation and durability are important when evaluating an optimum shield; these variables were not assessed and remain beyond the scope of this study. Clearly, they are important and deserve further study and attention.

In keeping with the ALARA principle, a responsible program fosters syringe shield use regardless of the additional burden to the technologist; and these burdens are minor in comparison to the alternative.

ACKNOWLEDGMENTS

The author would like to thank Ricky Zane Carrol for his technical support, Lisa Holcomb for her research assistance, and the staff at Meritus Health Systems for their aid in preparing this study.

REFERENCES

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