July 6, 2010

Regional Administrator
NRC Region III
2443 Warrenville Road
Lisle, Illinois 60532

Dear Sir,

Based on NRC Confirmatory Order (IA-09-026) issued to me on July 28, 2009, I have agreed within 45 days following each periodic (quarterly) Radiation Safety Committee meeting, to provide minutes of the meeting to the permitee, the NHPP, and the NRC. Enclosed is a copy of the signed minutes from the May 27, 2010 Radiation Safety Committee meeting with attachments. I have checked with the VA local Privacy Officer and Regional Counsel, and the minutes can be made available to the public per the Order.

If you have any questions, please contact me at 859-381-5929.

Sincerely,

Michael T. Hackett, MS

Enclosure

cc: Acting Director, VA Medical Center, Lexington, Kentucky (electronic copy)
Director, National Health Physics Program (electronic copy)

Radiation Safety Committee (RSC) Minutes
May 27, 2010

AGENDA ITEM	DISCUSSION	ACTION & TRACKING #	TARGET
Review of Minutes			
1. Review of minutes from March 4, 2010 RSC meeting Dr. Baker	RSC Signed Minutes Link to minutes as Word file with embedded attachments Link to minutes as pdf file with bookmarked attachments The minutes were reviewed by RSC prior to this meeting & obtaining signatures. They were presented at April 2010 Environment of Care Council. The minutes were approved by all members present.	Complete May 2010	N/A
Old Business			
1. RSC Performance Goals for 2010 Dr. Baker & M. Hackett	**a. Finalize Closeout Survey Procedure for the Medical Center** Approved at the March 4, 2010 RSC meeting & posted on the public drive.	Complete Mar 2010	N/A
	b. Deactivation of Several Inactive Labs in Research Six research labs (C309, C314, C323A, D301A, D305, D310) are currently inactive and are awaiting close-out surveys to allow the RSC to release these areas for unrestricted use. Nuclear Medicine technical staff to assist RSO.	Perform close out surveys of 2 labs **OB-1b-05.27.2010**	Aug 2010 M. Hackett
	c. Complete of the Re-Approval Process of Authorized Users in Research Two re-approvals are pending RSO summaries for the RSC review.	Complete summaries for RSC review **OB-1c-05.27.2010**	Aug 2010 M. Hackett
	d. Further Enhance Radiation Safety Training to Include Radiographic-Fluoroscopic Use Areas Pending development of training for rad-fluoro use areas.	Develop training for rad-fluoro use areas **OB-1d-05.27.2010**	Dec 2010 M. Hackett
	e. Develop Prostate Brachytherapy (contract) Quarterly Review Complete and now a Standing Agenda Item.	Complete May 2010	N/A
	f. Develop a Dose Alert During Cardiac Cath Procedures Plus an Automatic Review of Cases >10 Gy Dose alert & automatic review agreed upon, awaiting implementation.	Implement dose alert & automatic review process **OB-1f-05.27.2010**	Aug 2010 M. Hackett & Dr. Ziada
	g. Develop Training for RSC Concerning Radiation Emergency Response Radiation Emergency tabletop exercise to be held involving Police and ED personnel later this summer. RSC members expressed interest in being notified and invited to participate. Discussed various aspects of this training that will include references & resources (e.g., NHPP, REAC/TS, CDC, etc) as they pertain to radiation emergency response plus general information concerning radiation & radiation safety.	Complete and distribute Radiation Emergency Reference Card to RSC members. **OB-1g-05.27.2010**	Jul 2010 M. Hackett & B. Wierzbinski

AGENDA ITEM	DISCUSSION	ACTION & TRACKING #	TARGET
2. Updating MCM 00-27 Dr. Baker	MCM 00-27 03.18.2010 This updated MCM was approved at the March 4, 2010 RSC meeting. It was then sent for administrative review &it was posted as of March 18, 2010; although, additional changes will be needed due to new RSC requirements (see New Business - 7. Prescriptive Requirements for Radiation Safety Committee).	Complete Mar 2010	N/A
3. Repeated CTs Dr. Baker	Patient Safety Review The Committee discussed patient safety's review & recommendations. The RSC decided that the first two recommendations are not warranted at this time since this case was a patient driven incident according to patient safety. The last recommendation was put into effect by Radiology and Clinical Applications group prior to Safety Committee review. (i.e., when a provider selects a CT that is being ordered, prior similar CTs are displayed giving the date(s) done along with interpretations) & has been shared with other VAs. The Committee agreed by all members present that no further action was needed.	Complete May 2010	N/A
4. Ni-63 Source Disposal M. Hackett	RSO reported the 2 no longer used Ni-63 ECD sources were sent for disposal in May.	Complete May 2010	N/A
5. Tabletop Exercise on Radiological Emergency Response B. Wierzbinski	It was reported that the tabletop will occur in July. In addition to the tabletop, several pre-tabletop exercises will occur (e.g., ED understanding of radiological emergency response, Police commandeering of survey meters in research, Nuclear Medicine staff monitoring techniques) that will include pre and post training evaluations.	Complete tabletop exercise & pre-tabletop exercises, invite RSC members to participate **OB-5-05.27.2010**	Jul 2010 B. Wierzbinski & M. Hackett
Standing Agenda Items			
1. Quarterly Radiation Safety Audits for Jan-Mar 2010 Dr. Baker & M. Hackett	**Area Detailed Audits:** Nuclear Medicine; Research; Rad-Fluoro Use; ALARA-Rad Exp; Prostate Brachytherapy	Continue to monitor as part of the qtrly audits	Aug 2010 M. Hackett

AGENDA ITEM	DISCUSSION	ACTION & TRACKING #	TARGET
	Area Trending Reports with Deficiency Summary, Notable Changes & Updates, and Pending Items:  Qtrly Trending Report The Committee discussed the above area detailed audits and trending reports along with any actions and changes that were required & have been already have been taken:		

Area	Deficiency Summary
Nuclear Medicine	• Missed daily dose calibrator constancy check 1 time - staff training done. No further action necessary per RSC consensus.
Research	• No deficiencies
Rad-Fluoro Use	• Pelvis CT radiation was higher than expected - found "smart MA" was not set for those patients so the acquisition protocol was changed. • Average dose for CTA Aorta w/ Runoff was slightly higher when compared to 2009 - delayed post contrast CT had been added to the protocol & started use of lower kVp on patients w/BMI <25 which will lower dose on these select cases. • Two cases in Specials were slightly >3 Gy - both cases required extended fluoro time but were over various areas & used multiple projections. • Fifty-four cath lab cases showed potential absorbed doses ≥3 Gy but <10 Gy. These are based on corrected air kerma values and assume no movement of the x-ray tube or the patient during the entire case which overestimatesactual skin absorbed dose for these cases (and the majority of all cardiac cath cases). The number of cases in this range was similar to 2009 average of 55 per qtr. • Two interventional cath lab cases reported potential absorbed doses ≥10 Gy but <15 Gy & two interventional cath lab cases reported potential absorbed doses ≥15 Gy (15.3 & 15.7 Gy). Based on Cardiology's review of these cases that involved multiple projections the actual maximum skin dose in any one location is much less than the reported values & <15Gy for the two latter cases. There were no skin abnormalities on initial assessments and follow-up skin assessments are pending (see below). Cardiology was encouraged to reduce use of cine runs (using fluoro instead) when possible which should help decrease patient dose. Old Business 1.f. action will also improve this. • Seven cases involved effective doses ≥100 mSv (1 - Diagnostic, 5 - Interventional, 1 - Electrophysiology) - first qtr reviewed; continue to monitor.
ALARA-Rad Exp	• Two times the ALARA I levels were exceeded during Jan-Mar 2010 (i.e., anesthesiologist in the pain clinic exceeded the whole body effective dose equivalent & lens dose equivalent) - the RSO discussed these readings with the employee and gave him a written notification of these readings.

No further action needed per RSC consensus

N/A

AGENDA ITEM	DISCUSSION		ACTION & TRACKING #	TARGET
	Prostate BrachyTx	• One time implanted seeds found outside of the treatment area by non-VA institution's medical physicist - only 2 of the 77 implanted seeds (2.6%) while the VA radiologist's independent review did not consider them outside treatment area.		
	Area	**Notable Changes & Updates**	No further action needed per RSC consensus	N/A
	Nuclear Medicine	• Updated software for uptake/well system to include ability to measure & quantify internal organ burden after a radiological event. • Fabricated two new replacement lead containers with chained clips on lead tops for use with two Co-57 spot markers. • VA Police performed the annual Physical Security Survey for Nuclear Medicine - no violations found.		
	Research	• Replaced current volume labeling of vial with index card located in vial's re-sealable bag's document pouch.		
	Rad-Fluoro Use	• Chest CT w/o Contrast follow up review had lower average effective dose when compared to Jan-Mar 2009 review. • Abdomen CT w/o Contrast follow up review had lower average effective dose when compared to Apr-Jun 2009 review. • Pelvis CT w/o Contrast follow up review had lower average effective dose when compared to Apr-Jun 2009 review. • Abdomen CT w/ & w/o Contrast Liver Protocol follow up review had lower average effective dose when compared to Jan-Mar 2009 review. • Changed trending audit to display only quarterly data (i.e., no monthly breakdown) to be consistent with other trending audits. • Added CT Radiation Summary Charts as part of CT Review. • Added monitoring of effective doses as part of the Cardiac Cath review and a related reference. • Changed breakdown of Cardiac Cath review from by room to by procedure type (Diagnostic, Interventional, Electrophysiology).		
	ALARA-Rad Exp	• Added links in trending/detailed reports to staff exposure trending reports for employees who exceed ALARA during the year.		
	Prostate BrachyTx	• Developed trending report & detailed audit for prostate brachytherapy which included data from 2008-2009.		
	Area	**Pending Items (new trending report for 2010)**	Follow up on the pending 5 patient reviews **SAI-1-PI-05.27.2010**	Aug 2010 M. Hackett
	Nuclear Medicine	• N/A		
	Research	• N/A		

AGENDA ITEM	DISCUSSION		ACTION & TRACKING #	TARGET
	Rad-Fluoro Use	• Pending 2 patient reviews (i.e., >14 week skin assessment) by cardiologist of cases involved absorbed doses ≥10 Gy but <15 Gy. • Pending 2 patient reviews (i.e., >14 week skin assessment) by cardiologist of cases involved absorbed doses ≥15 Gy.		
	ALARA-Rad Exp	• N/A		
	Prostate BrachyTx	• Pending 1 patient review by VA urologist of post prostate brachytherapy.		
2. Summary of Dosimetry Results for Workers Dr. Baker	As discussed above in the ALARA-Radiation Exposure detailed audit & trending report, 2 times the ALARA I levels were exceeded during Jan-Mar 2010 (i.e., anesthesiologist in the pain clinic exceeded the whole body effective dose equivalent & lens dose equivalent).		Continue to monitor as part of the qtrly audits	Aug 2010 M. Hackett
3. Status of All Procedures Requiring a Written Directive Dr. Baker	As noted above in the Nuclear Medicine detailed audit & trending report, all procedures requiring written directives (8) were reviewed for the period of Jan-Mar 2010. No problems were identified.		Continue to monitor as part of the qtrly audits	Aug 2010 M. Hackett
4. Status of Footprint Management Dr. Baker	Closeout surveys are pending for 6 research labs that are currently inactive for radioactive materials use. This is being followed as part of the RSC Performance Goals for 2010 (OB-1b-05.27.2010). No new areas of use were proposed.		Continue to monitor as part of the Performance Goals	Aug 2010 M. Hackett
5. Status for Security Dr. Baker	As noted above in the Nuclear Medicine & Research detailed audits & trending reports, all sealed sources were accounted for. As noted in the old business (item 4), 2 no longer used Ni-63 ECD sources have been sent off for disposal. It was noted that the VA Police performed the annual Physical Security Survey for Nuclear Medicine (see attachment in the above Nuclear Medicine detailed audit) and no violations were found. No security problems were identified.		Continue to monitor as part of the qtrly audits	Aug 2010 M. Hackett
New Business				
1. Reports of Spills and Incidents Dr. Baker	As noted above in the Nuclear Medicine & Research detailed audits & trending reports, no spills or other incidents were reporting during Jan-Mar 2010.		Continue to monitor as part of the qtrly audits	Aug 2010 M. Hackett
2. Self-Identified Radiation Safety Program Deficiencies Dr. Baker	No self-identified radiation safety program deficiencies were found at this time.		Continue to monitor as part of the qtrly audits	Aug 2010 M. Hackett

AGENDA ITEM	DISCUSSION	ACTION & TRACKING #	TARGET
3. Results for External Audits or Inspections Dr. Baker	**a. VHA Pharmaceutical Management Assessment - Aug/Sept 2009** Pharmaceutical Mgmt Assessment VHA Pharmaceutical Management Assessment performed by Booz Allen Hamilton in Aug-Sep 2009 report noted that "Nuclear Medicine/Radiopharmaceuticals Specific Considerations" was listed under "Pharmaceutical Handling and Use Exemplary Practices". No recommendations noted for radiopharmaceutical use.	Complete May 2010	N/A
	b. Joint Commission Life Safety Consultant Visit - Oct 2009 JC Life Safety Consultant Visit Joint Commission Life Safety Consultant Visited in Oct 2009. One action required pertained to the notation of the fabric condition when performing the annual lead apron review (i.e., not actually a radiation safety issue since it deals with the outer fabric only). This was added to the annual review starting in Nov 2009. Of the 3 "best practices" noted, one included radiation safety ("Hot Lab - control of hot material from use to disposal; apron log was one of the tighter systems observed"). No other recommendations noted for radiation safety.	Complete May 2010	N/A
4. Clinical Authorized User Approval Dr. Baker	This was an agenda item from the March 4 RSC meeting that was not covered then due to meeting time constraints. Dr. Oates from University of Kentucky previously requested RSC approval to become a clinical Authorized User at the VA. This request is currently is not needed & will be brought to the RSC in the future if needed.	Complete May 2010	N/A
5. Research Authorized User Amendments Dr. Baker	This was an agenda item from the March 4 RSC meeting that was not covered then due to meeting time constraints. It was noted that any changes to research Authorized User approvals will require an amendment(s) that will be similar to the initial application. No current amendments are required.	Complete May 2010	N/A
6. Security for Radioactive Materials for VHA Facilities Dr. Baker	**DUSHOM Memo 04.19.2010** Security for Radioactive Materials **Lexington VA Response to VISN9** Security for Rad Mat - Lex VAMC	Complete May 2010	N/A

AGENDA ITEM	DISCUSSION	ACTION & TRACKING #	TARGET
	The attached DUSHOM memo dated April 19, 2010 was discussed along with our response to our VISN regarding our radioactive materials and security provisions that are in place during their use and storage. This issue will be a Standing Agenda Item for this Committee (Status for Security - see above). No security problems were identified.		
7. Prescriptive Requirements for Radiation Safety Committee Dr. Baker	**New Requirements**  RSC Requirements **Updated MCM 00-27 (2nd update for 2010)**  MCM 00-27 Second Update **E-mail RSC Review**  E-mail RSC Review for RSC Members **Additional references as needed:**  VHA Directive 1105.01 10.07.09  NUREG-1556 Vol 11 Sec 8.7  10 CFR 33.13  10 CFR 35.24  NUREG-1516 Sec 1-4 The RSC discussed the new prescriptive requirements for the Committee (see attached) and the updated MCM 00-27 to reflect these new requirements. The MCM updates were approved by all Committee members present. Additional discussion was made concerning adding an additional RSC member from another Service other than Radiology that has radiographic-fluoroscopic use (e.g., Cardiology). This change to the MCM membership section was made after the meeting and sent for the Committee's review via e-mail. Five members reviewed & approved the change in the member listing. The updated MCM will be sent for administrative review and final posting.	Modify wording for recommended membership & send for RSC vote - Complete Jun 2010 Send for administrative review & final posting **NB-7-05.27.2010**	Jun 2010 M. Hackett & Public Affairs Officer
8. RSO Training M. Hackett	**RSO Requirements for Audits, Reviews, Records or Reports - May 19, 2010**  RSO Reports & Records It was noted that VHA Nuclear Medicine & Radiation Safety Services (115B) just presented their first training session (see attached) for Radiation Safety Officers via a webcast in May. M. Hackett, RSO and Dr. Brown for the RSC attended this training. This training will be tracked on the annual radiation safety training log & will be reported quarterly on the most appropriate detailed audit.	Complete May 2010	N/A
9. Other Dr. Baker	The Committee had no other new business.	Complete May 2010	N/A

Radiation Safety Committee (RSC) Minutes
May 27, 2010

Items Referred for Higher Level/Council Review and/or Other Committee Review

- The minutes from this meeting are regularly scheduled to be presented during the June 2010 Environment of Care Council meeting.

Next Meeting – August 26, 2010 @ 11:30 in Nuclear Medicine Conference Room, B101A – Tentative Agenda

Review of minutes from May 27, 2010 RSC meeting

Old Business

1. **RSC Performance Goals for 2010 (a. & e. are complete)**
   - b. **Deactivation of Several Inactive Labs in Research (OB-1b-05.27.2010)**
   - c. **Complete of the Re-Approval Process of Authorized Users in Research (OB-1c-05.27.2010)**
   - d. **Further Enhance Radiation Safety Training to Include Radiographic-Fluoroscopic Use Areas (OB-1d-05.27.2010)**
   - f. **Develop a Dose Alert During Cardiac Cath Procedures Plus an Automatic Review of Cases >10 Gy (OB-1f-05.27.2010)**
   - g. **Develop Training for RSC Concerning Radiation Emergency Response (OB-1g-05.27.2010)**
2. **Tabletop Exercise on Radiological Emergency Response (OB-5-05.27.2010)**
3. **Quarterly Radiation Safety Audits for Jan-Mar 2010 - Pending 5 Patient Reviews (SAI-1-PI-05.27.2010)**
4. **Prescriptive Requirements for Radiation Safety Committee (NB-7-05.27.2010)**

Standing Agenda Items

1. **Quarterly Radiation Safety Audits for Apr-Jun 2010**
2. **Summary of Dosimetry Results for Workers**
3. **Status of All Procedures Requiring a Written Directive**
4. **Status of Footprint Management**
5. **Status for Security**

New Business

1. **Reports of Spills and Incidents**
2. **Self-Identified Radiation Safety Program Deficiencies**
3. **Results for External Audits or Inspections**
4. **Other**

Attendance & Minutes Tracking:	Meeting Time:	Recorder:
Sign In Sheet; Attendance & Minutes Tracking	1:00 pm - 2:05 pm	Michael T. Hackett, MS

Recommend Approval / ~~Disapproval~~

Michael T. Hackett, M.S.
Radiation Safety Officer

6/9/10
Date

Recommend Approval / ~~Disapproval~~

Cheryl D. Baker, M.D.
Chief of Radiology
Radiation Safety Committee Chair

6/9/10
Date

Recommend Approval / ~~Disapproval~~

W. Keith Neeley, Acting Associate Director for
Donna K. Jacobs, FACHE
Associate Director
Radiation Safety Committee Management Representative

6/9/10
Date

Recommend Approval / ~~Disapproval~~

Sally M Higgins, CSP, CFPS
Safety & Occupational Health Manager
Environment of Care Council Co-Chair

6/10/10
Date

and / ~~or~~

Recommend Approval / ~~Disapproval~~

W. Keith Neeley, Acting Associate Director for
Donna K. Jacobs, FACHE,
Associate Director
Environment of Care Council Co-Chair

6/10/10
Date

Approved / ~~Disapproved~~

Donna K. Jacobs, FACHE, Acting Director

6/14/10
Date

Radiation Safety Committee (RSC) Minutes
March 4, 2010

AGENDA ITEM	DISCUSSION	ACTION	TARGET
Current Old Business			
1. Previous Minutes – Dr. Baker	**Minutes from December 30, 2009 meeting** (reviewed by RSC prior to obtaining signatures - presented at January 2010 Environment of Care Council) RSC Signed Minutes Link to minutes with attachments	No further action required	Complete
2. Closeout Surveys – S. Brown & M. Hackett (10 minutes)	**Closeout Surveys SOP & Research Lab Deactivation** Closeout Survey Methods - NHPP Closeout Surveys SOP RSC discussed the SOP that was taken from the NHPP recently revised (Dec 2009) guidelines for closeout survey methods. The SOP was approved by all Committee members present (6) and will be posted in radiation safety folder on the public drive. As discussed in the December 2009 RSC meeting, 6 research labs (C309, C314, C323A, D301A, D305, D310) that are currently inactive for radioactive materials use will have closeout surveys done for the RSC's approval to release for unrestricted use. A large amount of dedicated RSO time is required to properly perform the closeout surveys along with the required documentation (>40 hrs).	Perform closeout surveys on 6 labs with quarterly RSC updates – M. Hackett (will be followed in old business performance goals)	Dec 2010
3. Brachytherapy – Dr. Baker & M. Hackett (5 minutes)	**Prostate Brachytherapy** Seed Location Review 2008-2009 RSC discussed the seed location review done by VA Radiologist on the 12 VA patients who had prostate brachytherapy done at an outside institution in 2008-2009. The Committee agreed that contractor performance was very good . The Committee recommended that we continue reviewing these cases.	Develop quarterly audit which will include seed location & medical reviews – M. Hackett (will be followed in new business qtrly review)	May 2010
4. Back-up for RSO – Dr. Baker & M. Hackett (2 minutes)	**Back-up RSO Options** Dr. Baker reported on discussion with the UK Radiation Safety Officer, and the committee identified 3 options for temporary RSO coverage, should an urgent need arise. Options include: University of Kentucky radiation safety, a local radiation physics group, VA RSOs at other facilities (Louisville). If the need occurs, the RSC should consult with NHPP & meet to further discuss immediate options.	No further action required	Complete

Radiation Safety Committee (RSC) Minutes
March 4, 2010

AGENDA ITEM	DISCUSSION	ACTION	TARGET
5. 1105.01/MCM 00-27 – V. Kiefer & M. Hackett (2 minutes)	**Revised VHA Directive 1105.01 (i.e., Updating MCM 00-27)** VHA Directive 1105.01 10.07.2009 · MCM 00-27 RSC 10.24.2007 · RSC MCM 00-27 2010 Update RSC discussed the updated RSC MCM. Minor changes to the October 2007 MCM were done to reflect the recent minor changes in VHA Directive 1105.01 (i.e., updated file - red highlights are items to be changed/removed with yellow highlights being updated/additional items). The MCM updates were approved by all Committee members present (6) and will be sent for administrative review and posting.	Administrative review & posting – Public Affairs Officer	Apr 2010
6. Res AU Renewals – Dr. Baker & M. Hackett (5 minutes)	**Renewal of Research Authorized User Applications** Drs. Ain & VanderWesthuyzen's renewal applications will be sent via e-mail for RSC review & approval.	Renewal applications sent via e-mail – M. Hackett (will be followed in old business performance goals)	Apr 2010
7. Repeated CTs – Dr. Baker & M. Hackett (2 minutes)	**Repeated CTs** CT Exam Repeat Corrective Action As discussed in the December 2009 RSC meeting, a young female patient had three CTs within 3 weeks. Per the RSC recommendation, this case was reported to the Office for Quality and Safety for their review. As of this meeting, no official results of their review were available for the RSC. Our local Clinical Applications group has developed a process (i.e., attached MRI procedure prototype) when a selected radiology procedure is being ordered, the prior similar procedure(s) will be displayed giving the date(s) done along with the interpretation. This process will implemented locally for various CT exams and has been shared with other VAs.	Follow up with Office for Quality and Safety for their review – D. Jacobs	May 2010
8. Previous Qtrly Audits – Dr. Baker & M. Hackett (5 minutes)	**Follow up on Previous Qtrly Audits** a. Patient Radiation Exposure in Cath & EP Labs Dr. Baker and Mike Hacked reported on their meeting with Cardiology. Cardiology agreed to implement a 3-6-9 Gy dose alert to cardiologist during procedures and to provide additional cardiology fellow radiation safety training as well as a process for patient follow-up for patients receiving high radiation doses. b. Cath & EP lab staff ALARA findings Cath lab nurse manager discussed radiation exposure with nurse. No one monitored in cath lab exceeded 10% of the annual occupational limits in 2009.	a. Develop 3-6-9 Gy dose alert & patient follow up criteria – M. Hackett/Dr. Ziada (will be followed in old business performance goals) b. No further action required	Apr 2010 Complete

Radiation Safety Committee (RSC) Minutes
March 4, 2010

AGENDA ITEM	DISCUSSION	ACTION	TARGET
9. Performance Goals – Dr. Baker & M. Hackett (10 minutes)	**RSC Performance Goals for 2009** These goals were discussed as part of the annual review below.	Continue to monitor progress of performance goals – M. Hackett	May 2010
Current New Business			
1. Qtly Audits – Dr. Baker & M. Hackett (5 minutes)	**Quarterly Radiation Safety Audits for Oct-Dec 2009** Combined Trending Report with Summaries with Detailed Areas Audits Qtrly Trending Report; Nuclear Medicine; Research; Rad-Fluoro; ALARA-Rad Exp This quarterly review was discussed as part of the annual review below.	Continue to monitor as part of the qtrly audits – M. Hackett	May 2010
2. Annual Review – Dr. Baker & M. Hackett (10 minutes)	**Comprehensive Radiation Safety Program Annual Review for Calendar Year 2009** Comprehensive Review for 2009; RSC e-mail Review Discussion included several items from the annual review: • RSC met qtrly w/ quorum present & minutes presented to Environment of Care Council • Radiation safety training completed in 2009 • NRC NOV in April 2009 w/ our NOV reply in May 2009 • Performance goals completed, ongoing, terminated, and additional ones for 2010 • Highlights from deficiency summaries (e.g., local radiopharmacy return package documentation, patient radiation doses from cardiac cath), and notable changes and updates (e.g., Nuclear Medicine ALARA). Although this annual review and the Oct-Dec quarterly audits were available to the RSC prior to the meeting and reviewed in part at this meeting, minor changes to the annual review were made and sent out after the meeting to RSC along with the quarterly audits for further RSC review. These reviews/audits along with their actions and changes were approved by e-mail by all Committee members who were present (6) at this meeting (see attached "RSC e-mail Review"). After this meeting the annual review was presented to the Environment of Care Council and was approved by the Medical Center Director (see attached signed annual review).	Continue to monitor the radiation safety program through progress of performance goals and by the qtrly audits – M. Hackett	May 2010
3. Clinical AU – Dr. Baker & M. Hackett (2 minutes)	**Clinical Authorized User Approval** Due to meeting time constraints, this item will be carried over as new business at the next RSC meeting.	Discuss at next meeting – M. Hackett	May 20190

Radiation Safety Committee (RSC) Minutes
March 4, 2010

AGENDA ITEM	DISCUSSION	ACTION	TARGET
4. Res AU Amendment – Dr. Baker & M. Hackett (2 minutes)	**Research Authorized User Amendments** Due to meeting time constraints, this item will be carried over as new business at the next RSC meeting.	Discuss at next meeting – M. Hackett	May 2010
5. Tabletop Rad Emerg – Dr. Baker & M. Hackett (2 minutes)	**Tabletop Exercise on Radiological Emergency Response**  Tabletop - Rad Emerg Response It was noted that a tabletop exercise involving radiological emergency response is being developed for use in 2010. RSC committee members agreed that additional emergency response training is desired for all RSC members. Discussion included possibility of including a guest to give a presentation at the next RSC meeting.	Follow up at next meeting – M. Hackett	May 2010
6. Ni-63 Sources – Dr. Baker & M. Hackett (2 minutes)	**Ni-63 Source Disposal** Due to meeting time constraints, this item was address to the RSC via e-mail shortly after this meeting. The RSO requested the RSC's approval to properly dispose of 2 Ni-63 ECD sources that are no longer in use. This was approved by e-mail by all Committee members who were present (6) at this meeting (see New Business item 2 attached "RSC e-mail Review").	Dispose of Ni-63 sources – M. Hackett	Apr 2010
7. Interventional CT – Dr. Baker & M. Hackett	**Interventional CT Review** Due to meeting time constraints, this item although not listed on the agenda was address to the RSC via e-mail shortly after. The request to discontinue the 100% review of all Interventional CT cases. Of the 153 interventional CT cases in 2009, 145 (95%) were for cardiac CTA with an average patient effective dose (mSv) of 9.7 mSv which is within reported values in the literature (i.e., 5-32 mSv) while the non-Cardiac patient doses were lower. This was approved by e-mail by all Committee members who were present (6) at this meeting (see New Business item 2 attached "RSC e-mail Review").	Drop Interventional CT review from qtrly audit – M. Hackett	Complete

Items Referred for Higher Level/Council Review and/or Other Committee Review

- The radiation safety annual review is regularly scheduled to be presented during the March 2010 Environment of Care Council meeting
- The minutes from this meeting are regularly scheduled to be presented during the April 2010 Environment of Care Council meeting.

Radiation Safety Committee (RSC) Minutes
March 4, 2010

AGENDA ITEM	DISCUSSION	ACTION	TARGET

Next Meeting – May 27, 2010 @ 11:30 am in Nuclear Medicine Conference Room, B101A

Next Meeting's Tentative Old Business including items from current agenda requiring further action (see above).
1. **Review of Previous RSC Minutes**
2. **RSC Performance Goals**
3. **Updating MC00-27**
4. **Repeated CTs**
5. **Ni-63 Source Disposal**
6. **Tabletop Exercise on Radiological Emergency Response**

Next Meeting's Tentative New Business
1. **Quarterly Audit Review**
2. **Clinical Authorized User Approval**
3. **Research Authorized User Amendments**

Attendance:	Meeting Time:	Recorder:
Sign In Sheet; RSC Dates and Attendance for 2009	1:00 pm – 2:00 pm	Michael T. Hackett, MS

Recommend Approval / ~~Disapproval~~

Michael T. Hackett, M.S., Radiation Safety Officer

Recommend Approval / ~~Disapproval~~

Cheryl D. Baker, M.D. Chief of Radiology/RSC Chair

Recommend Approval / ~~Disapproval~~

Donna K. Jacobs, FACHE, Associate Director/RSC Management Representative

Approved / ~~Disapproved~~

Sandy J. Nielsen, FACHE, Director

VA MEDICAL CENTER
LEXINGTON, KENTUCKY

MEMORANDUM NO. 00-27
MARCH 18, 2010

RADIATION SAFETY COMMITTEE

1. PURPOSE: To delegate responsibilities and define membership of the Radiation Safety Committee (RSC) at the Lexington VA Medical Center.

2. POLICY: This VA Medical Center will have a hospital wide committee, which will oversee the radiation safety program.

3. RESPONSIBILITIES: The Radiation Safety Committee and Radiation Safety Officer function together to support the Director and take all actions necessary to ensure the safe use of radioactive materials and regulatory compliance. In the usual organizational arrangements, the Radiation Safety Officer completes day-to-day actions with oversight by the Radiation Safety Committee. Overall, the actions by the Radiation Safety Committee and Radiation Safety Officer must include, but not be limited to:

a. Provides oversight for the safe use of radioactive materials with a focus to ensure occupational and public doses are ALARA and a safety conscious work environment is achieved.

b. Establishes committee membership to include the Chair, Radiation Safety Officer, a management representative, a representative for each type of authorized use including Research Service, and a representative from Patient Care Services.

c. Holds meetings that are scheduled on a recurring date during each quarter that is set by the committee. These meetings must have a quorum present of at least one-half of the committee membership and must include the Chair (or designee), Radiation Safety Officer and a management representative (or designee). If a meeting is rescheduled or canceled, meeting intervals must not exceed 6 calendar months.

d. Prepares records and reporting committee results as required by executive management and/or Title 10 Code of Federal Regulations (CFR) 35; and ensures the records document executive management approvals for actions under 10 CFR 35 (e.g., 35.24 and 35.26).

e. Coordinates with other medical center committees/councils (e.g., Environment of Care Council, Research committees, GEMS, Emergency Management) as needed, and reports results of committee meetings to executive management or other medical center oversight committees/councils (e.g., Environment of Care Council).

f. Completes and/or provides oversight for the Radiation Safety Program through periodic reviews and audits, to include:

(1) Annual radiation safety program review per 10 CFR 20.1101 to include locations of use with emphasis on decommissioning records per 10 CFR 30.

(2) Reviews and/or audits, as needed, based on the radioactive materials scope of uses.

(3) Evaluates results from audits, reviews, and inspections to determine possible generic issues or trends, identify root causes, specify corrective actions and actions to prevent recurrence, and determine if any results are applicable to other uses of radioactive materials.

(4) Distributes the results of audits, reviews, and inspections to all work centers and makes available to the staff working with, or around, radioactive materials.

(5) Oversees and follows up on resolutions of health and safety issues, and radiation safety program deviations, as needed.

g. Reviews at least every 6 months, occupational and public doses.

h. Reviews at least every 6 months, any identified health and safety issues or possible radiation safety program deviations from regulatory compliance or required practices.

i. Reviews and approves training and experience for prospective Radiation Safety Officers, authorized users, and/or other staff requiring regulatory approval.

j. Reviews and approves proposed changes to training, equipment, facilities, and radiation safety procedures or practices.

k. Ensures sealed source inventories are completed:

(1) Quarterly, for sealed sources with either current activity greater than one millicurie or current activity greater than 1000 times the quantities in 10 CFR 20, Appendix C

(2) Semiannually, for all other sealed sources, except sources specifically exempted by CFR 30.

l. Ensures sealed source records are maintained for transfer or disposition to document leak test results, if the sealed source was required by regulation or permit condition to have leak testing.

m. Provides results for sealed source inventories and leak tests to the NHPP, if requested.

n. Provides oversight for security of radioactive materials by:

(1) Compliance with regulations per 10 CFR 20.1801, 10 CFR 20.1802, and 10 CFR 37 (when issued).

(2) Prevention of adversary or unauthorized removal of radioactive materials.

(3) Compliance with the security guidelines in VHA Handbook 1200.06.

(4) Focusing on adequate security commensurate with possible risks of radioactive materials unauthorized use.

o. Classifies sealed sources, not in active use for their intended clinical or research purpose for a period of 24 months, as disused sources and evaluates the disused sources for disposal as expeditiously as possible.

p. Reviews and evaluates research protocols by:

(1) Complying with regulations per 10 CFR 35.6 for radioactive materials use in human subject research.

(2) Complying with guidelines for obtaining and documenting research informed consent as required by VHA Handbook 1200.5.

q. Uses the Nuclear Regulatory Commission documents (NUREG-1556 series) as guidance to prepare and submit requests for new, renewed, or amended permits.

r. Restricts radiation safety program implementation to be consistent with the program codes (i.e., broad-scope medical or research uses) and permits conditions approved for the permittee.

s. Ensures approvals for authorized users and locations of use (except as authorized per 10 CFR 35.14) are limited to broad-scope permittee.

t. Ensures compliance with posting requirements per 10 CFR 19 and 21.6, as in the following:

(1) VHA Radioactive Material Permit No. 16-08896-04 issued under VHA Nuclear Regulatory Commission License No. 03-23853-01VA authorizes the use of radioactive materials at this location. Contact [*current Radiation Safety Officer's name*] at [*insert current location information such as room number, mail stop, or telephone number*] to examine the permit and supporting documents.

(2) VHA license, amendments, and supporting application available for examination by contacting the NHPP at (501) 257-1571, or at mailing address NHPP (115HP/NLR), Bldg 101, Room 208, 2200 Fort Roots Drive, North Little Rock, AR 72114.

u. Provides information to workers at the various locations of use or work centers, especially satellite locations of use, on current radiation safety program and regulatory issues, as needed, using the NHPP intranet Web site, periodic newsletters, and other information resources made available to permittees.

4. PROCEDURES:

a. The Chair, Radiation Safety Committee, and Radiation Safety Officer will have stop work authority and direct access to the Director.

b. The minutes of each meeting will be recorded and sent to the Medical Center Director for approval through the Committee Chair and the Associate Director. After the Director's approval, the minutes will be reported to the Environment of Care Council for review. The minutes will be distributed to the Committee members, Chair of the Environment of Care Council, Chief of Staff, Chief of Nuclear Medicine, and the ACOS/Research.

c. Membership:
Radiation Safety Officer
Member from Management
Member from Nuclear Medicine Service (physician, Clinical authorized user)

Member from Nuclear Medicine Service (technical staff)
Member from Patient Care Services
Member from Research Service (research authorized user)
Member from a clinical service involved with non-radioactive ionizing radiation (physician)
Member from a clinical service involved with non-radioactive ionizing radiation (technical staff)
NAGE Safety Officer
(Names of actual members and appointments by the Director will be on file in the Radiation Safety Office.)

5. REFERENCES: VHA Directive 1105.1 Management of Radioactive Materials dated October 7, 2009; Title 10 Code of Federal Regulations; VHA Permit number 16-08896-04; NUREG-1556 Volumes 7, 9, and 11.

6. FOLLOW-UP RESPONSIBILITY: Chief, Radiology Service or designee.

7. RECERTIFICATION: This memorandum is due for review and recertification by March 18, 2013, in accordance with procedures in Medical Center Memorandum 001-01.

Sandy J. Nielsen, FACHE
Director
VAMC Lexington

From: Peppiatt, Jennifer
Sent: Friday, February 26, 2010 3:25 PM
To: Dunn, Edward J (LEX)
Subject: RE: too much radiation

Dr. Dunn,
After reviewing this case and discussing it with several providers as well as Mike Tackett (Nuclear Medicine) there are a few recommendations that I would suggest.
First, this episode of repeated CT scans appears to be "patient driven", actually she presented a 4th time to the ED with the same complaints and they refused to do the CT scan so she left our facility and went to UK to be evaluated and was CT'd there as well. She also is receiving care at St. Joe's and Harrison Memorial as she felt we were not addressing her issues. She was scheduled for multiple PC/ GYN and Urology appts which she no-showed for which made it very difficult to care for her as she continued to use the ED for her primary care but never followed up for further testing to address her flank pain, dysuria, etc.
There is no set limit of CT's that patients can have per year according to Mike Tackett however the provider should be weighing risks vs. benefits.
Recommendations:
We could possibly require patients who receive repeated CT scans to sign a consent depicting risks/benefits in the long run.
Education could always be helpful if Radiology could provide us with the info we could send it out to Service Chiefs and have the providers read the material however as stated I feel that some of these cases are "patient driven" and the provider must do the exam needed in order to treat the patient.
My final recommendation is that we institute a flag system in CPRS which would denote if multiple CT's are ordered when the provider is trying to enter a new order, just as we have flags to alert us when meds are contraindicated in the pharmacy package.
Let me know if you would like me to do anything further.
Jennifer

Radiation Safety Committee
Detailed Audit for Jan-Mar 2010
Nuclear Medicine

1. **Daily Radiation Surveys:**
   - Performed daily as required including weekend/holiday studies: Yes — If no, explain below.
   - Any areas greater than trigger level (TL): No — If yes, explain below.
     - Hot Lab - 0 times, Imaging Room - 0 time, Injection Room - 0 times:
   - If areas were greater than TL, was appropriate action taken to decrease radiation levels below TL: N/A — If no, explain below.

2. **Weekly Radiation Wipes:**
   - Performed weekly as required: Yes * — If no, explain below.
     * 03/05 - Wipes printout was not retained but there was documentation that the wipes were done with results of nothing >TL. Discussed with the nuclear medicine technologists involved about retaining the wipes printouts.
   - Any areas greater than trigger level (TL): No — If yes, explain below.
     - Hot Lab - 0 time, Imaging Room - 0 times, Injection Room - 0 times:
   - If areas were greater than TL, was appropriate action taken to decrease radiation levels below TL: N/A — If no, explain below

3. **Item Currently Not Tracked (Mo-99/Tc-99m Assays - discontinued use in June 2008 due to revised USP <797>)**

4. **Daily Dose Calibrator Constancy Checks (for Capintec CRC-15R & CRC-35R dose calibrators):**
   - Performed daily if used for pts as required including weekend/holiday studies: No x1 — If no, explain below.
     - 01/07- Daily constancy check was not completely done (i.e., "Daily" test procedure was documented as done and only 1 (Cs-137 which is the radioactive standard used) of 4 radionuclide settings documented as checked & it was within limits) on the non-Tc-99m dose calibrator (i.e., CRC-15R). Based on the patient schedule for that day, only one patient study involving Tl-201 assays (x2) was performed that required that dose calibrator. The RSO discussed this issue with the nuclear medicine technologist involved. Since a similar incident occurred in December 2009, all nuclear medicine technical staff reviewed a radiation safety refresher presentation on this subject in April 2010 (see attached).

     
     Nucl Med Refresher Training
   - Performed quarterly full constancy check: Yes — If no, explain below.
   - Constancy checks were within established limits: Yes — If no, explain below.

5. **Quarterly Dose Calibrator Linearity Checks (for Capintec CRC-15R & CRC-35R dose calibrators):**
   - Performed quarterly (due 1st month of qtr) or after repair as required: Yes — If no, explain below.
   - Linearity checks were within established limits: Yes — If no, explain below.

6. **Annual Dose Calibrator Accuracy Checks (for Capintec CRC-15R & CRC-35R dose calibrators):**
   - Performed annually as required (due in Sept. or after repair): N/A — If no, explain below.
   - Accuracy checks were within established limits: N/A — If no, explain below.

7. **Dose Calibrator Geometry Checks (for Capintec CRC-15R & CRC-35R dose calibrators):**
   - Performed as required (after repair): N/A — If no, explain below.
   - Accuracy checks were within established limits: N/A — If no, explain below.

8. **Daily Thyroid Probe/Well Counter and Multi-Well Counter Constancy Checks:**
   - Performed daily as required (i.e., when used): Yes — If no, explain below.
   - Constancy checks were within established limits: Yes — If no, explain below.

9. **Quarterly Thyroid Probe/Well Counter (MDA, chi-square) and Multi-Well Counter (normalized, chi-square) Checks:**
   - Performed quarterly (due 1st month of qtr) or after repair as required: Yes — If no, explain below.
   - Checks were within established limits: Yes — If no, explain below.

Radiation Safety Committee
Detailed Audit for Jan-Mar 2010
Nuclear Medicine

10. Monthly Xenon Machine Quality Control Checks:

- Performed monthly/quarterly or after repair as required: Yes — If no, explain below.
- Quality control checks were within established limits: Yes — If no, explain below.

11. Semi-Annual Air Flow Measurements (AFM) & Xenon Spill Clearance Time Calculations/Annual Fume Hood Certification:

- Semi-annual AFM performed as required (due in Jun. & Dec.): N/A — If no, explain below.
- Imaging room & hot lab under negative pressure & confirmed by smoke test: N/A — If no, explain below.
- Xenon spill clearance times calculated and posted after AFM made: N/A — If no, explain below.
- Annual fume hood certification performed (due in Feb.): Yes — If no, explain below.
- Fume hood sash level noted after calibration made: Yes — If no, explain below.

12. Annual Survey Meter Calibrations:

- Performed annually as required (due in Mar. or after repair): Yes — If no, explain below.
  - 6 survey meters: 4 GM survey meters with 1 having 2 probes, 1 ion chamber, and 1 sodium iodide survey meter.

13. Quarterly/Annual Radionuclide Sealed Source Inventory:

- Performed quarterly (due 1st month of qtr) as required: Yes — If no, explain below.
- All sources accounted for: Yes — If no, explain below.
  - 139 sealed sources (since previous inventory, received two new Co-57 spot markers on 01/08/10).
- Performed monthly check of Cs-137 calibration source: Yes — If no, explain below.
- Annual NHPP sealed source verification performed as required (due in Mar.) Yes — If no, explain below.
  - 2 sealed sources.

14. Semi-Annual Radionuclide Sealed Source Leak Testing:

- Performed semi-annually as required (due in Jan. & Jul.): Yes — If no, explain below.
  - 3 sealed sources leak tested.
- Any leakage detected above required limits: No — If yes explain below.

15. Reportable or Recordable Events/Incidents:

- Any reported reportable or recordable events/incidents: No — If yes, explain below.

16. Reported Radioactive Spills:

- Any reported radioactive spills: No — If yes, explain below.

17. Quarterly Review of In-coming Radionuclide Receiving Records:

- Any receiving record missing pertinent info (e.g., survey/wipe results): No — If yes, explain below.
- Any problems noted (e.g., contamination, wrong material): No — If yes, explain below.
  - 214 in-coming shipments with 196 being from local radiopharmacy.
  - Total activity received in the above shipments based on radionuclide

Radionuclide	mCi
Co-57	0.1
Ga-67	10.1
I-131 (in Capsule)	251.0
In-111	7.2
Tc-99m	22,440.6
Tl-201	39.7
Xe-133	548.3

18. Quarterly Review of Out-going Radionuclide/Return Package Records:

- Any out-going record missing pertinent info (e.g., survey/wipe results): No — If yes, explain below.
- Any problems noted (e.g., contamination): No — If yes, explain below.
- 196 out-going packages:
  - 196 return packages to local radiopharmacy.
- Did return packages to local pharmacy equal the amount received: Yes — If no, explain below.

Radiation Safety Committee
Detailed Audit for Jan-Mar 2010
Nuclear Medicine

19. Written Directive (WD) Audits for Nuclear Medicine: x8

Compared WD on file in Radiation Safety Office to radionuclide receipt and use records, and if applicable, Radiation Safety therapy patient file, and immediate/delayed patient release file.

Pt.(see RSO file)	Radionuclide & Procedure	Date	WD mCi	Given mCi	Comments	* Problems
	I-131 Whole Body	01/04/10	5.6	5.6	Written revision of WD (5.0 mCi to 5.6 mCi) done by Authorized User before administration due to the availability of I-131 dose amount.	None
	I-131 Thy CA Rx	01/06/10	100.0	99.3	Pt. released immediately based on pt. a specific calculation which is on file. Pt. given required written radiation safety instructions.	None
	I-131 HyperThy Tx	02/09/10	10.0	10.67	Pt. given required written radiation safety instructions.	None
	I-131 Whole Body	02/22/10	5.0	5.4	N/A	None
	I-131 Thy CA Rx	02/24/10	100.0	103.0	Pt. released immediately based on pt. a specific calculation which is on file. Pt. given required written radiation safety instructions.	None
	I-131 HyperThy Tx	03/02/10	16.0	15.9	Female: Patient questioned and responded that she was not pregnant or breast feeding plus patient had a negative HCG the morning of the treatment before dosing. Pt. given required written radiation safety instructions.	None
	I-131 Whole Body	03/17/10	5.0	5.04	N/A	None
	I-131 Whole Body	03/24/10	5.7	5.6	Written revision of WD (5.0 mCi to 5.7 mCi) done by Authorized User before administration due to the availability of I-131 dose amount.	None

*e.g., WD incomplete, patient identity not verified by two methods, dose not within ±10% of prescribed dose, etc.

- I-131 Whole Body - 4, I-131 Hyper Thy Tx - 2, I-131 Thy CA Tx - 2.
- Any problems noted. No If yes, explain below.

20. Training (Include all staff if dealing with clinical use of radionuclides.): Yes x149.00 If yes, attach list.

- DOT HAZMAT refresher training (i.e., every 3 yrs) for Nuclear Medicine staff is due by September 21, 2010 (i.e., last done on 09/21/07) or initial training for new staff within 90 days.

21. Radiation Safety Improvements and/or Additional Comments/Problems: Yes x3 If yes, explain below.

- Feb - BioMed loaded software update on uptake/well counter system which included ALERT software (see attachment) that will allow us to measure and quantify internal organ burden after a radiologic event. This software update was funded by DEM/LFUCG emergency management funds along with 4 pocket dosimeters.

ALERT System Software Upgrade

- Feb - Engineering fabricated two new replacement lead containers (see attachment) with chained clips on lead tops for use with two Co-57 spot markers (exempt sources).

Spot Marker Holders

- Feb - VA Police performed the annual Physical Security Survey for Nuclear Medicine (see attachment). No violations were found.

Physical Security Survey

Audit performed by: Michael T. Hackett, MS, Radiation Safety Office

Radiation Safety Committee
Detailed Audit for Jan-Mar 2010
Nuclear Medicine

Radiation Safety Training:

#	Date	Time	# Staff	# hrs/ Staff	Total # hrs	Type	Section/Service	Training Title (click on the below links to view training)
N/A	Jan	N/A	1	1.00	1.00	PP/T	EMS	2009 Annual Radiation Safety Training - EMS
N/A	Jan	N/A	1	1.00	1.00	PP/T	Safety Office	2009 Annual Radiation Safety Training - AOD
N/A	Feb	N/A	1	1.00	1.00	PP/T	Nuclear Medicine	Radiation Safety Training - Nuclear Medicine
N/A	Feb	N/A	5	0.50	2.50	PP/H	Nuclear Medicine	Nuclear Medicine Refresher - 2010 - Radioactive Shipment Receipt from Local Radiopharmacy and Return
N/A	Feb	N/A	1	0.50	0.50	PP/H	Radiation Safety	Nuclear Medicine Refresher - 2010 - Radioactive Shipment Receipt from Local Radiopharmacy and Return
N/A	03/15/10	N/A	1	10.00	10.00	LMS	Nuclear Medicine	IS-3 Radiological Emergency Management (FEMA - Emergency Management Institute)

16.00 Grand Total of # Training hrs.

N/A = if not a RSO Lecture/Training Session (e.g., viewed video, special lecture, review material, or read article and took test)

Key:	Type of training
A/T =	Article & Test - Self Review
H/T =	Handout & Test - Self Review
L =	Lecture with PowerPoint presentation/Handout
LMS =	LMS Training

Key:	Type of training
OST/PP =	Off Site Training PowerPoint presentation
P/E =	Procedure and/or Equipment Review
PP/H =	PowerPoint presentation/Handout - Self Review

Key:	Type of training
PP/T =	PowerPoint presentation/Handout - Self Review with Test
R =	Review of Records and Procedures - Self Review
V =	Video - Self Review

Daily Dose Calibrator Constancy Checks

- This refresher training deals with daily dose calibrator constancy checks
- Quick overview
  - Two dose calibrators
    - Capintec CRC-35R on "Tc-99m side"
    - Capintec CRC-15R on "non-Tc-99m side"
      - CRC-15R may not be used daily for patients but testing should still be done

  - Perform & document the "Daily" tests & Cs-137 std measurements on the various settings
  - If not w/i set limits, STOP, DO NOT USE & notify RSO

Review of Constancy Records

- Recent radiation safety audits have found:

Radiation Safety Committee
Trending Quarterly Audit for 1st Qtr 2010
Nuclear Medicine Service

Click on the links to the right for the detailed Quarterly Nuclear Medicine Service Radiation Safety Audits in 2010 or the Trending Report for 2009 (on far right) which includes links to 2009 detailed audits	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	2009 Qtrly Average	2009 Total
4 Daily Dose Calibrator (DC) Constancy Checks (2 dose calibrators):								
# of times constancy checks not performed daily if used for pts as required	1							
# of times quarterly full constancy check not performed	0				0.0	0	0.0	0
# of times constancy checks not within limits	0	-	-	-	0.0	0	0.0	0

  - # of times constancy checks not performed (i.e., see below) daily when the dose calibrator used for patients: 1 time in 2010 & 1 time in 2009
    (i.e., so near - January) (December)
    - Each time above involved Capintec CRC-15R & check was started but not completed (only 1 setting checked)

Daily Checks

- When performing daily dose calibrator constancy checks before the patients arrive
  - Check both dose calibrators every work day!
    - Consider doing the "non-Tc-99m" dose calibrator first so it is not overlooked
    - Consider not multi-tasking during the checks (i.e., start the check & run it to completion without doing another task in between settings - this was the problem here: **started but not completed**)
  - This should eliminate the problem
    - If its done, its done!

But what if its not done?

CRC-15R Dose Calibrator

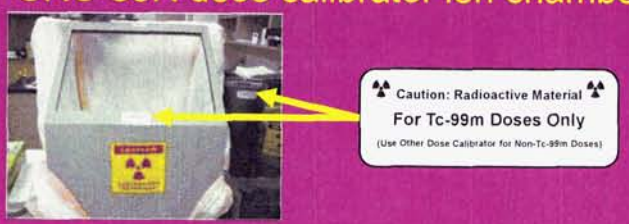
- When using the "non-Tc-99m" dose calibrator
  - Check the constancy log to see if it has been done before using (e.g., Xe-133, I-131, Tl-201, Ga-67, etc…)
  - If not done, perform the constancy check before using
  - Reminder labels on the "non-Tc-99m" L-shield & CRC-15R dose calibrator ion chamber

Caution: Radioactive Material
For Other Radionuclide Doses Only (i.e., Non-Tc-99m)
(Use Other Dose Calibrator for Tc-99m Doses)

Check & make sure that the daily constancy has been completed before using this dose calibrator.

CRC-35R Dose Calibrator

- Please remember that the "Tc-99m" dose calibrator should be for Tc-99m based radiopharmaceuticals only
  - Use the CRC-15R, for all other radionuclides
  - Reminder labels on the "Tc-99m" L-shield & CRC-35R dose calibrator ion chamber



Daily Dose Calibrator Constancy Checks

- Chances are our dose calibrators will constantly give us correct readings but we need to ensure they do by performing daily constancy checks
  - Thank you for assistance with this matter!

Training Credit

- Please complete the below training credit form & return it to the RSO for
  - 15 minutes of training for this presentation:

- Click here to e-mail the RSO a Question Concerning this Training

- Thank you

ALERT System Software Upgrade
(Item #0960-0177)
Available to all Captus® 3000 Users

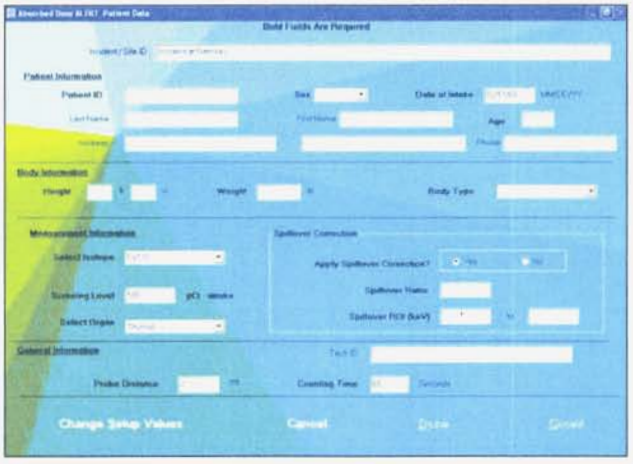
In an emergency involving release of radioactive materials, internal contamination due to inhalation is a potential health concern. When a large population is potentially impacted, a critical public health challenge is to provide an initial field screening to rapidly triage and identify individuals with significant amounts of internal contamination. Capintec is proud to announce a measurement solution to this challenge.*

Captus® 3000 Alert Software adds this valuable feature to your Captus® 3000 system, providing dual functionality for both routine and emergency requirements. The system can measure and quantify internal organ burden after a radiologic event and perform all standard thyroid uptake, bioassay and MCA functions routinely required in a Nuclear Medicine department. The Emergency Population Screening module records demographic data, calculates BMI values and selects appropriate body type and generates results in µCi intake.

Measurements may be performed at thyroid, outer thigh and back of right lung, and data are currently available for Co-60, Ir-192, Cs-137 and I-131. The software utilizes conversion factors to calculate µCi-intake values from 1 to 30 days after intake. Results will be flagged when user defined trigger levels are exceeded. Those values which exceed limit are displayed in RED, and those under limit are displayed in GREEN. User can modify default measurement protocols as required to accommodate individual variability.

Collimated and shielded detector provides enhanced sensitivity. Can detect 1 ALI (Annual Limit of Intake) up to 30 days after intake within sixty seconds.

The Custom Protocol program supports customized measurements and calculations by integrating predefined measurement screens with Microsoft Excel® for analysis and report generation. This feature is ideal for post event data analysis.



Software Features:

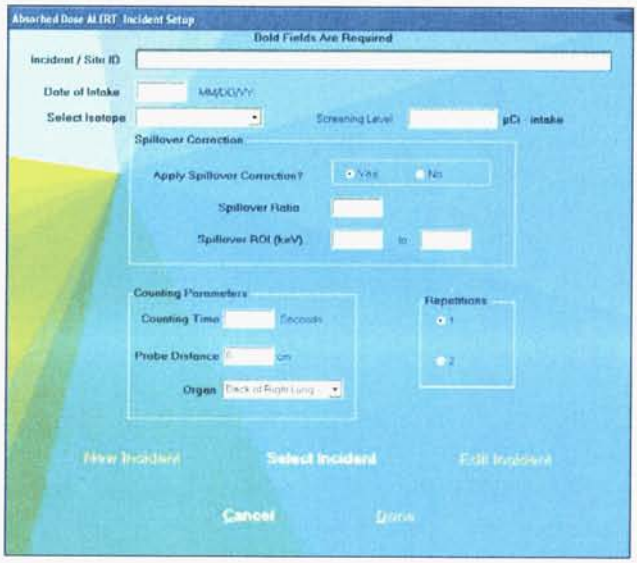
- Stores patient demographic data, measurements and calculated results
- Detects one ALI in 60 seconds or less up to 30 days after intake
- Multiple prompts assure user friendly format
- Automatically calculates Body Mass Index (BMI)
- Selects appropriate conversion factors* based on BMI
- Calculates µCi-intake at elapsed time after event
- Data currently available for following categories:
- Isotopes: Co60, Ir192, Cs137, and I131
  - Organ sites: thyroid, lung, and outer thigh
  - Elapsed time: day 1 through day 30 after intake
  - Results flagged in RED if values exceed trigger levels
- Enhanced archive, storage and data retrieval features
- Specialized export features transfer data directly to Excel®
- Flexible report formats, detailed and summary
- Custom Protocol module
- Fully automated quality assurance program including:
  - Calibration
  - Resolution
  - Constancy
  - Chi-square
  - MDA
  - Efficiencies
- 1024 channel MCA with manual and automated controls
- Password protected
- Includes all of the Captus® 3000 software programs
  - Thyroid uptake with multiple protocol choices
  - Wipe Tests
  - Bioassay
  - Lab tests
  - Isotope Library
  - Quick Start Menu

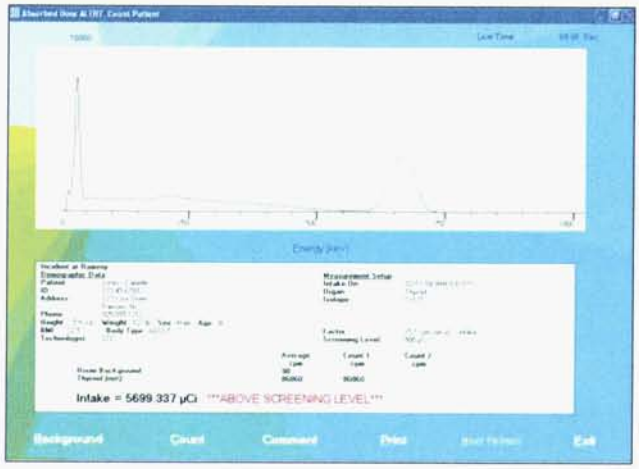
*This product was developed using physical measurements on Capintec's Captus 3000 and computer modeling data developed at Georgia Institute of Technology with support and research funded by the Centers for Disease Control and Prevention.

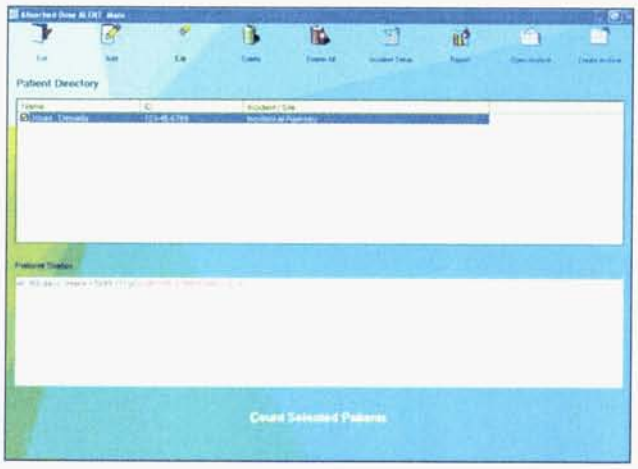
Note: Additional ingestion data pending

CAPINTEC, INC. 6 Arrow Road, Ramsey, NJ 07446 • PH: 201.825.9500 or 800.631.3826 • WEB: www.capintec.com

ALERT System Software Upgrade
(Item #0960-0177)
Available to all Captus® 3000 Users







Capintec, Inc.
6 Arrow Road
Ramsey, NJ 07466 USA
Phone: 1-800-631-3826
www.capintec.com

Absorbed Dose ALERT Summary

Incident at Ramsey
Smith , John 987-65-4321
Intake On: 02/11/08 Measured: 02/11/09 16:20 (MM/DD/YY)
366 days Thyroid Cs137
4030cpm,net 266.887 µCi - intake ***BELOW SCREENING LEVEL***
Comment: None

Incident at Ramsey
Jones , Danielle 123-45-6789
Intake On: 02/11/08 Measured: 02/11/09 16:14 (MM/DD/YY)
366 days Thyroid Cs137
86060cpm,net 5699.337 µCi - intake ***ABOVE SCREENING LEVEL***
Comment: None

Absorbed Dose ALERT Report

Incident at Ramsey

Demographic Data
Patient: Jones , Danielle
Patient ID: 123-45-6789
Address: 123 Your Street
Ramsey, NJ
Phone: 925-555-1212
Height: 5 ft 3 in **Weight:** 127 lb **Sex:** Male **Age:** 36
BMI: 22.5 **Body Type:** ADULT
Technologist: SCC

Measurement Setup
Intake On: 02/11/08 (MM/DD/YY)
Organ: Thyroid
Isotope: Cs137

Factor: 15.1 cpm per µCi - intake
Screening Level: 500 µCi

Measurement at 366 days
Time: 02/11/09 16:14 (MM/DD/YY hh:mm)

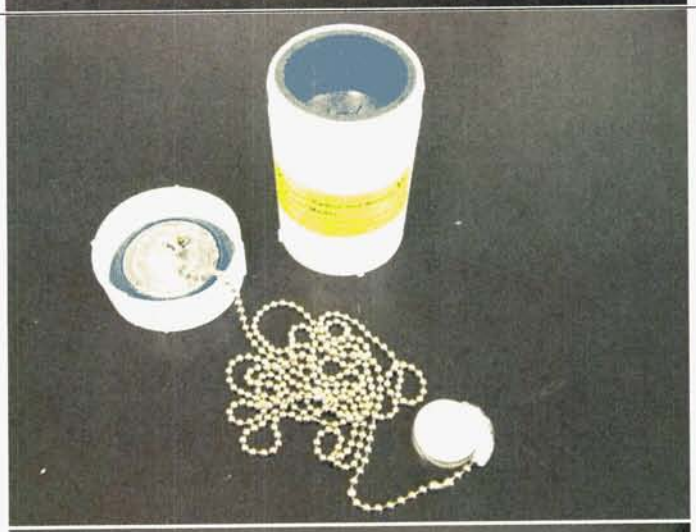
	Average cpm	Count 1 cpm	Count 2 cpm
Room Background:	90		
Thyroid (net):	86060	86060	
Intake = 5699.337 µCi	***** ABOVE SCREENING LEVEL *****		

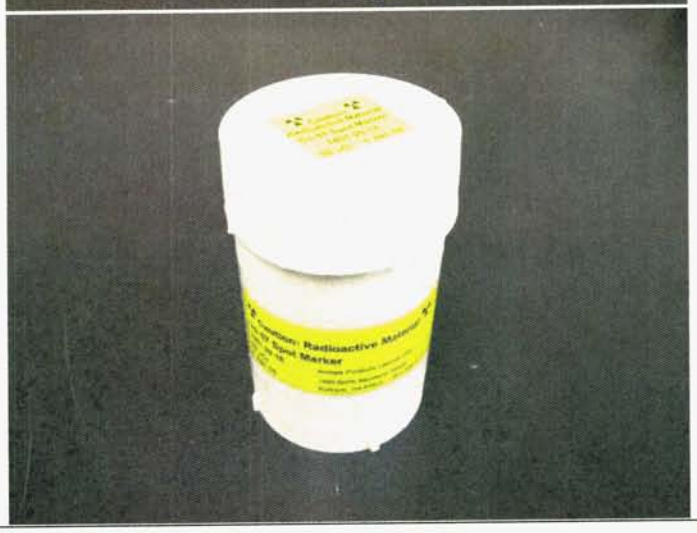
Old Co-57 spot marker holder:

Chain attached to lead container and is on the outside when not in use.

New Co-57 spot marker holder:

Chain attached to lead top and is on the inside of lead container when not in use.





DEPARTMENT OF VETERANS AFFAIRS

MEMORANDUM

Date: February 19, 2010

From: Physical Security Officer (O7B)

Subject: Physical Security Survey

To: Chief, Nuclear Medicine (115)
Thru: Associate Medical Center Director (001)
Thru: Chief, Police Service (O7B)

1. **PURPOSE:** To advise the results of the Physical Security Survey of your Radiation High Risk and Low Risk areas for the medical center that was conducted on February 19, 2010.

2. **SCOPE:** Radiation High Risk and Low Risks areas CD division.

3. **FINDINGS:**

    a. CD:

        1. No violations noted.

        2. Staff is aware of procedure to notify police during emergencies.

4. **RECOMMENDATIONS:** None

5. **CONCLUSIONS**: All requirements are satisfactory.

Physical Security Survey: Radiation High and Low Risk Storages Areas

Alonzo D. Alcern, Captain
Physical Security Officer

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1. **Monthly Radiation Surveys/Wipes of Core Labs, Waste, Common Areas done by Radiation Safety Office:**
   - Performed monthly: Yes — If no, explain below.
   - Any areas greater than trigger level (TL): No — If yes, explain below.
   - If areas were greater than TL, was appropriate action taken to decrease radiation levels below TL: N/A — If no, explain below.

2. **Annual Radiation Surveys/Wipes of each Authorized User Lab/Room done by Radiation Safety Office:**
   - Performed in December: N/A — If no, explain below.
   - Any areas greater than trigger level (TL): N/A — If yes, explain below.
   - If areas were greater than TL, was appropriate action taken to decrease radiation levels below TL: N/A — If no, explain below.
   - Number of Rooms: N/A Number of Authorized Users: N/A

3. **Quarterly Record Audit of Weekly Radiation Wipes Performed by each Authorized User Labs:**
   - Performed weekly if radioactivity is used: Yes * — If no, explain below.
   - * 02/05 - Wipes printout was not retained but there was documentation that the wipes were done with results of nothing >TL. Discussed with the research lab staff person involved about retaining the wipes printouts.
   - Any areas greater than trigger level (TL): No — If yes, explain below.
   - If areas were greater than TL, was appropriate action taken to decrease radiation levels below TL: N/A — If no, explain below.
   - Number of Rooms: 13 (2 never activated) Number of Authorized Users: 10

4. **Quarterly/Annual Radionuclide Sealed Source Inventory of Labs and Core Labs done by Radiation Safety Office:**
   - Performed quarterly as required: Yes — If no, explain below.
   - All sources accounted for: Yes — If no, explain below.
     - 17 sealed sources.
   - Annual NHPP sealed source verification performed as required (due in Mar.) Yes — If no, explain below.
     - 2 sealed sources.

5. **Semi-Annual Radionuclide Sealed Source Leak Testing done by Radiation Safety Office:**
   - Performed semi-annually as required (due in Jan. & Jul.): Yes — If no, explain below.
     - 2 sealed sources leak tested.
   - Any leakage detected above required limits: No — If yes explain below.

6. **Quarterly Radionuclide (Unsealed) Inventory of each Authorized User Lab done by Radiation Safety Office:**
   - All sources accounted for: Yes — If no, explain below.
   - All Authorized Users within possession limits: Yes — If no, explain below.
   - Number of Authorized Users: 10 As of: January 1, 2010

7. **Reported Radioactive Spills:**
   - Any reported radioactive spills: No — If yes, explain below.

8. **Authorized User Lab Closings:** No — If yes, explain below.

9. **Annual Survey Meter Calibrations:**
   - Performed annually as required (due in Mar. or after repair): Yes — If no, explain below.
     - 5 survey meters: 1 new meter that was a replacement, 1 old deactivated meter with new pancake probe was recalibrated, 1 new meter for lab that is to be activated in the future.

10. **Annual Beta Counter (2) Quench Curve and Gamma Counter (2) Calibration:**
    - Performed annually (due in Jan. or after repair): Yes — If no, explain below.
      - 5 survey meters: 1 new meter that was a replacement, 1 old deactivated meter with new pancake probe was recalibrated, 1 new meter for lab that is to be activated in the future.

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11. Monthly Beta Counter (2) Normalization, Chi-Square, and Constancy Checks and Gamma Counter (2) Peak, % Resolution, Chi-Square, Constancy, and Efficiency Checks:

- Performed monthly — Yes — If no, explain below.
- All checks were within established limits: — Yes — If no, explain below.

12. Authorized User Approvals/Re-approvals by Radiation Safety Committee: Yes x1 If yes, explain below.

- Jan - 1 Authorized User was re-approved by the RSC via e-mail voting.

Authorized User	Radionuclide(s)	Max. mCi	Procedure Type(s)	Lab(s)
Stephen Brown, Ph.D.	Cr-51	10	In Vitro	C311A (previously active lab)
	H-3	10	In Vitro	C311B (previously active lab)
	P-32	10	In Vitro	

13. Quarterly Review of In-coming Radionuclide Receiving Reports:

- Any shipments received that were not pre-approved by RSO: — No — If yes, explain below.
- Any receiving report missing pertinent info (i.e., survey/wipe results): — No — If yes, explain below.
- Any problems noted (i.e., contamination, wrong material): — No — If yes, explain below.
- 1 shipments with 1 order

Radionuclide	# Shipments	mCi
P-32	1	0.37

14. Quarterly Review of Out-going Radionuclide Package Records:

- Any out-going record missing pertinent info (e.g., survey/wipe results): — N/A — If yes, explain below.
- Any problems noted (e.g., contamination): — N/A — If yes, explain below.
- None to report.

15. Training (Include all staff if dealing with research use of radionuclides.): Yes x17.25 If yes, list on last page.
See Nuclear Medicine audits for support staff (e.g., EMS, Police, etc.)

16. Radiation Safety Improvements and/or Additional Comments/Problems: Yes x1 If yes, explain below.

- Mar - Replaced labeling of radionuclide vial with current volume information with a 4x6 index card with pertinent radionuclide information that is located in the vial's re-sealable bag's document pouch. This will allow the user to document each radionuclide use and it will serve as a backup for the radionuclide use & disposal form which was also updated so pertinent radionuclide information can be electronically entered when received (see attached).


Current Volume Info

Audit performed by: Michael T. Hackett, MS, Radiation Safety Office

Radiation Safety Committee
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Radiation Safety Training:

#	Date	Time	# Staff	# hrs/ Staff	Total # hrs	Type	Section/Service	Training Title (click on the below links to view training)
N/A	Jan	N/A	1	0.25	0.25	V	Research	2009 Annual Radiation Safety Training - Research: • Practicing Safe Science (Howard Hughes Medical Institute) **
N/A	Jan	N/A	1	0.25	0.25	V	Research	• Radionuclide Hazards (Howard Hughes Medical Institute)
N/A	Jan	N/A	2	0.25	0.50	PP/H	Research	Research Emergency & Safety Procedures (2009 version) * (FYI for Other Research Staff)
1	01/29/10	9:20 AM	1	1.50	1.50	L	Research	Initial Radiation Safety Training: • Initial Radiation Safety Training - Research
N/A	Feb	N/A	1	0.25	0.25	PP/H	Research	Research Emergency & Safety Procedures (2009 version) * (FYI for Other Research Staff)
N/A	Mar	N/A	26	0.25	6.50	PP/H	Research	Research Emergency & Safety Procedures (2009 version) * (FYI for Other Research Staff)

9.25 Grand Total of # Training hrs.

* Note of the 60 minutes of this research safety training, about 15 minutes would pertain to radiation safety.

** Note of the 30 minutes of this research safety video, about 15 minutes would pertain to radiation safety.

N/A = if not a RSO Lecture/Training Session (e.g., viewed video, special lecture, review material, or read article and took test)

Key:	Type of training
A/T =	Article & Test - Self Review
H/T =	Handout & Test - Self Review
L =	Lecture with PowerPoint presentation/Handout
LMS =	LMS Training

Key:	Type of training
OST/PP =	Off Site Training PowerPoint presentation
P/E =	Procedure and/or Equipment Review
PP/H =	PowerPoint presentation/Handout - Self Review

Key:	Type of training
PP/T =	PowerPoint presentation/Handout - Self Review with Test
R =	Review of Records and Procedures - Self Review
V =	Video - Self Review

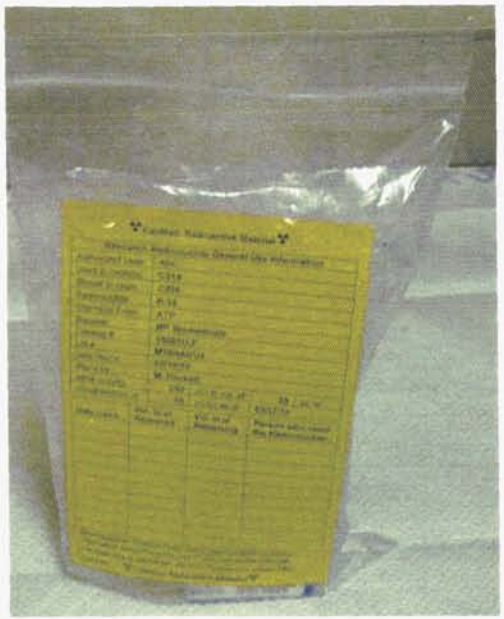
Previously current volume documented on label placed on research radionuclide vial:

~1.0" x 1.3" label

☢ Caution: Radioactive Material ☢
Isotope: _____
Current Vol: _____µl
Initials: _____
Date: _____
See manufacturer/lab diluted label for more info (e.g., chemical form, concentration, calibration date, etc.).

User would complete new label and place over old label after each use. Some problems with label staying on the vial especially when stored in -70° freezers.

March 2010, current volume documented on 4"x6" index card with pertinent radionuclide information located in research radionuclide vial's re-sealable bag's document pouch:



☢ Caution: Radioactive Material ☢

Research Radionuclide General Use Information				
Authorized User	Ain			
Used in room(s)	C318			
Stored in room	C326			
Radionuclide	P-32			
Chemical Form	ATP			
Supplier	MP Biomedicals			
Catalog #	35001U.2			
Lot #	M10HAGU3			
Date Rec'd	03/19/10			
Rec'd by	M. Hackett			
Initial activity	250	µCi in vol. of	25	µl; w/
concentration of	10	µCi/µl as of	03/27/10	

Date Used	Vol. in µl Removed	Vol. in µl Remaining	Person who Used the Radionuclide

See Research Radionuclide Use & Disposal form for more information concerning the use of this radioactive material.
If another card is needed (i.e., no more space above), contact RSO.

Card #1 ☢ Caution: Radioactive Material ☢

☢ Caution: Radioactive Material ☢

Card #1 ☢ Caution: Radioactive Material ☢

This will allow the user to document each radionuclide use and it will serve as a backup for the radionuclide use & disposal form which was also updated so pertinent radionuclide information can be electronically entered when received:

Rev. 03/10 - MTH

Research Radionuclide Use & Disposal

Authorized User: **Ain**
Used in room(s): **C318**
Stored in room: **C326**

Radionuclide: **P-32**
Chemical Form: **ATP**
Supplier: **MP Biomedicals**
Catalog #: **35001U.2**
Lot #: **M10HAGU3**
Date Rec'd: **03/19/10**
Rec'd by: **M. Hackett**

INITIAL ACTIVITY INFORMATION

Initial activity **250** µCi in vol. of **25** µl; w/ concentration of **10** µCi/µl as of **03/27/10** *

If volume is modified, note this and recalculate the concentration.

USE INFORMATION * Decay correct the concentration using the calibration date noted above except for H-3 <1yr out & for C-14.				WASTE DISPOSAL INFORMATION Estimated amounts of removed activity that will be eventually in the following waste systems.				TRANSFER INFO If applicable.	REMAINING VOLUME INFO * If your calculated volume remaining does not correspond with the actual remaining volume, notify the RSO immediately.		
Date Used	Current Conc. * (µCi/µl)	Volume Removed (µl)	Activity Removed (µCi)	Dry Waste (µCi)	Liquid Waste (µCi)	Scint. Fluid Waste (µCi)	Other (µCi) Specify	Specify to what lab & amount in µCi (leave blank if not applicable)	* Volume Remaining (µl)	Used For (i.e., type of work)	Used By

If another page is needed (i.e., no more space above), contact the RSO.

Contact the RSO for pick up of remaining radionuclide (i.e., remaining unused volume or empty container).

Page #1

PICK UP INFORMATION

RSO will complete the information to the right & make a copy for your records.

Concentration of _____ µCi/µl as of _____ (i.e., pick up date) with a remaining volume of _____ µl & an activity of _____ µCi that was picked up by _____ and stored in _____ until final disposal.

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Use the links below for detailed case-by-case breakdown.

1. Patient radiation dose from CT (B152 only):

See reference tables/links at end of this audit related to patient effective doses.

CT Exams by Procedures:

Total	2976	Exams for 55 Procedures
Average	54.1	Exams/Procedure (note: patient may have multiple procedures; dose may reflect all exams done)

A. Item Currently Not Tracked (Interventional CT Exams - 2009: 100% initial monitoring; 2010: discontinue quarterly monitoring)

B.-D. CT Case Review Selection:

CT Radiation Summary Charts

B.-D. CT Radiation Summary Charts:

B. High Volume Cases (Sampling of different procedures reviewed each qtr - at least 2 per qtr):

(1) Broken down by Procedure Type: CT CHEST W/O CONTRAST (71250)

Effective Dose	mSv
Average	11.0
Minimum	5.7
Maximum	28.5
Total # of CT Cases (B152) Reviewed	30
# of cases ≥10 mSv but ≤100 mSv	16
# of cases >100 mSv	0

Follow up on Jan-Mar 2009 Audit:	*mSv*
Average	*15.4*
Minimum	*3.1*
Maximum	*46.7*
Total # of CT Cases (B152) Reviewed	*32*
# of cases ≥10 mSv but ≤100 mSv	*19*
# of cases >100 mSv	*0*

Initial audits; therefore, may have included other exams (e.g., abdomen, pelvis).

(2) Broken down by Procedure Type: CT ABDOMEN & PELVIS W/O CONTRAST (74150 & 72192)

Effective Dose	mSv
Average	17.5
Minimum	6.4
Maximum	31.4
Total # of CT Cases (B152) Reviewed	30
# of cases ≥10 mSv but ≤100 mSv	24
# of cases >100 mSv	0

C. Average Volume Cases (Sampling different procedures reviewed each qtr - at least 2 per qtr):

(1) Broken down by Procedure Type: CT CHEST, ABDOMEN & PELVIS W/O CONTRAST (71250, 74150 & 72192)

Effective Dose	mSv
Average	22.3
Minimum	8.6
Maximum	37.4
Total # of CT Cases (B152) Reviewed	30
# of cases ≥10 mSv but ≤100 mSv	25
# of cases >100 mSv	0

(2) Broken down by Procedure Type: CT ABDOMEN & PELVIS W/O CONTRAST (74150 & 72192)
with "CT ABD/PELVIS W/O CONT (RENAL STONE PROTOCOL)" orders & "Clinical History" of "30. Rule out kidney stones"

Effective Dose	mSv
Average	9.4
Minimum	6.0
Maximum	24.9
Total # of CT Cases (B152) Reviewed	30
# of cases ≥10 mSv but ≤100 mSv	7
# of cases >100 mSv	0

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D. Low Volume Cases (Sampling different procedures reviewed each qtr - at least 2 per qtr):

(1) Broken down by Procedure Type: CT ABDOMEN W/O CONTRAST (74150)

Effective Dose	mSv		Follow up on Apr-Jun 2009 Audit:	mSv	
Average	9.7		Average	18.6	Initial audits; therefore,
Minimum	2.5		Minimum	3.8	may have included
Maximum	16.1		Maximum	36.6	other exams (e.g.,
Total # of CT Cases (B152) Reviewed	21		Total # of CT Cases (B152) Reviewed	32	chest, pelvis).
# of cases ≥10 mSv but ≤100 mSv	12		# of cases ≥10 mSv but ≤100 mSv	24	
# of cases >100 mSv	0		# of cases >100 mSv		

(2) Broken down by Procedure Type: CT PELVIS W/O CONTRAST (72192)

Effective Dose	mSv		Follow up on Apr-Jun 2009 Audit:	mSv	
Average	13.7		Average	16.8	Initial audits; therefore,
Minimum	3.9		Minimum	3.8	may have included
Maximum	27.1		Maximum	36.6	other exams (e.g.,
Total # of CT Cases (B152) Reviewed	9		Total # of CT Cases (B152) Reviewed	32	chest, abdomen).
# of cases ≥10 mSv but ≤100 mSv	4	✓	# of cases ≥10 mSv but ≤100 mSv	22	
# of cases >100 mSv	0		# of cases >100 mSv		

✓ A few cases were higher than expected. Their acquisitions protocols were reviewed. It was determined that "smart MA" was not set to "on" in the protocol for those patients. The acquisition protocol was changed.

(3) Broken down by Procedure Type: CTA AORTA W/RUNOFF (75635)
limited to Abdomen-Pelvis (A-P) region only (i.e., excludes cases that include the entire chest and/or extremities)

Effective Dose	mSv		Follow up on Jan-Mar 2009 Audit:	mSv	
Average	38.6	✓	Average	36.3	Initial audits; therefore,
Minimum	14.6		Minimum	15.2	may have included
Maximum	59.9		Maximum	64.3	other exams (e.g.,
Total # of CT Cases (B152) Reviewed	18		Total # of CT Cases (B152) Reviewed	30	chest, extremities).
# of cases ≥10 mSv but ≤100 mSv	18		# of cases ≥10 mSv but ≤100 mSv	30	
# of cases >100 mSv	0		# of cases >100 mSv		

✓ Acquisition protocol had been changed (i.e., pts with BMI ≤25, kVp set @ 80) during this review period (i.e., late January 2010) which will lower the radiation dose to these patients (BMI ≤25), but additional delayed post contrast CT was added to the acquisition protocol for all patients during this review period (i.e., late February 2010).

(4) Broken down by Procedure Type: CT ABD W & W/O CONTRAST LIVER PROTOCOL (74170)

Effective Dose	mSv	Follow up on Jan-Mar 2009 Audit:	mSv
Average	25.6		43.3
Minimum	10.1		14.7
Maximum	46.2		86.9
Total # of CT Cases (B152) Reviewed	7		11
# of cases ≥10 mSv but ≤100 mSv	7		11
# of cases >100 mSv	0		0

2. Patient radiation dose from Interventional Fluoroscopy (Specials B180):

See reference table/link at end of this audit related to patient skin doses.

Fluoro Time	min		Absorbed Dose *	mGy	
Average	11.1	(1 Gy = 1,000 mGy)	Average	487	
Minimum	0.0		Minimum	2	
Maximum	71.4		Maximum	4,584	
Total # of Cases Reviewed	87		Total # of Cases Reviewed	87	
			# of cases ≥3 Gy but <10 Gy	2	✓
			# of cases ≥10 Gy but <15 Gy	0	
			# of cases over ≥15 Gy	0	

* Absorbed dose (i.e., total air kerma) at Interventional Reference Point (IRP) and assumes no movement of the x-ray tube and/or patient during the case.

✓ Two cases (i.e., right leg to foot, iliac & pelvic angiography with bilateral succ pta/stents & left iliac arteriogram and placement of thrombolysis infusion catheter) involved extended fluoro time (i.e., both ~71 minutes long) with absorbed doses slightly >3 Gy (i.e., 3.7 Gy & 4.6 Gy, respectively).

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3. Patient radiation dose from Cardiac Cath (A233 & A235, EP & Cardiac Cath Labs):
See reference table/link at end of this audit related to patient skin and effective doses.

Fluoro Time	min	Dose * mGy		Corrected Absorbed Dose **	mGy		Effective Dose ***	mSv	
Average	15.7	2,782	(1 Gy = 1,000 mGy)	Average	2,241		Average	30.6	
Minimum	0.0	2		Minimum	2		Minimum	0.1	
Maximum	115.0	19,492		Maximum	15,711		Maximum	162.6	
Total # of	214	214	Total # of Cases Reviewed		214		Total # of	214	
Cases		61	# of cases ≥3 Gy but <10 Gy		54	✓	Cases Reviewed		
Reviewed		3	# of cases ≥10 Gy but <15 Gy		2	✓	# of cases ≥10 mSv but ≤100 mSv	172	
		3	# of cases over [redacted] Gy		2	✓	# of cases >100 mSv	7	✓

* Dose (i.e., air kerma) at Interventional Reference Point (IRP) and assumes no movement of the x-ray tube and/or patient during the case.
** Corrected absorbed dose based on dose (i.e., air kerma) overestimation (i.e., 19.4% CCL & 19.6% EPL).
*** Effective dose based on E_{DAP} of 0.18 mSv/(Gy·cm^2) for coronary angiography from the Nordic report series on radiation protection issues, No 5.

✓ Fifty-four cases involved absorbed doses ≥3 Gy but <10 Gy that are based on corrected air kerma values and assume no movement of the x-ray tube or the patient during the entire case which would be highly unlikely (i.e., overestimation of highest actual skin absorbed dose for these cases and the majority of all Cardiac Cath cases).

✓ Two cases involved absorbed doses ≥10 Gy but <15 Gy & two cases involved absorbed doses ≥15 Gy.

Cardiology Review: "All of them were complex cases with difficult anatomy which prolonged the cases. However, all 4 cases were done in multiple camera projections, hence, the X-Ray beam was not concentrated in a single area of the skin." Based on the above review, both cases that were slightly >15 Gy (i.e., 15.3 Gy & 15.7 Gy) are assumed to have actual maximum skin dose of <15Gy.

Skin Assessment Review: Pending >14 week post case skin assessments.

✓ Seven cases involved effective doses ≥100 mSv (i.e., 1 - Diagnostic, 5 - Interventional, 1 - Electrophysiology).

A. Broken down by Procedure Type - Diagnostic:

Fluoro Time	min	Dose * mGy		Corrected Absorbed Dose **	mGy	Effective Dose ***	mSv
Average	8.5	1,860	(1 Gy = 1,000 mGy)	Average	1,498	Average	21.3
Minimum	1.1	22		Minimum	18	Minimum	0.6
Maximum	46.9	6,058		Maximum	4,883	Maximum	126.4
Total # of	94	94	Total # of Cases Reviewed		94	Total # of	94
Cases		11	# of cases ≥3 Gy but <10 Gy		8	Cases Reviewed	
Reviewed		0	# of cases ≥10 Gy but <15 Gy		0	# of cases ≥10 mSv but ≤100 mSv	76
		0	# of cases over ≥15 Gy		0	# of cases >100 mSv	1

B. Broken down by Procedure Type - Interventional:

Fluoro Time	min	Dose * mGy		Corrected Absorbed Dose **	mGy	Effective Dose ***	mSv
Average	23.5	4,976	(1 Gy = 1,000 mGy)	Average	4,009	Average	47.4
Minimum	0.0	2		Minimum	2	Minimum	0.1
Maximum	115.0	19,492		Maximum	15,711	Maximum	162.6
Total # of	76	76	Total # of Cases Reviewed		76	Total # of	76
Cases		48	# of cases ≥3 Gy but <10 Gy		44	Cases Reviewed	
Reviewed		3	# of cases ≥10 Gy but <15 Gy		2	# of cases ≥10 mSv but ≤100 mSv	68
		3	# of cases over ≥15 Gy		2	# of cases >100 mSv	5

C. Broken down by Procedure Type - Electrophysiology:

Fluoro Time	min	Dose * mGy		Corrected Absorbed Dose **	mGy	Effective Dose ***	mSv
Average	17.6	962	(1 Gy = 1,000 mGy)	Average	774	Average	21.5
Minimum	0.1	3		Minimum	2	Minimum	0.1
Maximum	76.0	5,682		Maximum	4,568	Maximum	110.5
Total # of	44	44	Total # of Cases Reviewed		44	Total # of	44
Cases		2	# of cases ≥3 Gy but <10 Gy		2	Cases Reviewed	
Reviewed		0	# of cases ≥10 Gy but <15 Gy		0	# of cases ≥10 mSv but ≤100 mSv	28
		0	# of cases over ≥15 Gy		0	# of cases >100 mSv	1

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4. Training (Include all staff if dealing with radiographic-fluoroscopic use.):	No		If yes, attach list.
5. Radiation Safety Improvements and/or Additional Comments/Problems:	Yes	x4	If yes, explain below.

- Changed trending audit to display only quarterly data (i.e., no monthly breakdown) to be consistent with other trending audits.
- Added CT Radiation Summary Charts as part of CT Review (item 1).
- Added monitoring of effective doses as part of the Cardiac Cath review (item 3) and a related reference (Table 3).
- Changed breakdown of Cardiac Cath review (item 3) from by room to by procedure type (Diagnostic, Interventional, Electrophysiology).

Audit performed by: Michael T. Hackett, MS, Radiation Safety Officer

Radiation Safety Committee
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Radiographic-Fluoroscopic Use

References with links for Section 1 above

Table 1. Relative radiation level designations along with common example examinations for each classification

Relative Radiation Level*	Effective Dose Estimate Range	Example Examinations
None	0	Ultrasound, MRI
Minimal	< 0.1 mSv	Chest radiographs, hand radiographs
Low	0.1-1 mSv	Pelvis radiographs, mammography
Medium	1-10 mSv	Abdomen CT, barium enema, nuclear medicine bone scan
High	10-100 mSv	Abdomen CT without and with contrast, whole body PET

*The RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, the region of the body exposed to ionizing radiation, the imaging guidance that is used, etc). The RRLs for these examinations are designated as NS (not specified).

Taken from ACR Appropriateness Criteria® Radiation Dose Assessment Introduction (Relative Radiation Level Information).

Table 2

Adult Effective Doses for Various CT Procedures

Examination	Average Effective Dose (mSv)	Values Reported in Literature (mSv)
Head	2	0.9–4.0
Neck	3	
Chest	7	4.0–18.0
Chest for pulmonary embolism	15	13–40
Abdomen	8	3.5–25
Pelvis	6	3.3–10
Three-phase liver study	15	
Spine	6	1.5–10
Coronary angiography	16	5.0–32
Calcium scoring	3	1.0–12
Virtual colonoscopy	10	4.0–13.2

Taken from Mettler FA, Jr., Huda W, Yoshizumi TT, Mahesh M. Effective doses in radiology and diagnostic nuclear medicine: a catalog. Radiology 2008; 248(1):254-263.

References with links for Sections 2 & 3 above

Table II. Radiation-Induced Skin Injuries

Effect	Typical Threshold Absorbed Dose (Gy)*	Hours of Fluoroscopic "On Time" to Reach Threshold** at Usual Fluoro Dose Rate of 0.02 Gy/min (2 rad/min)	Hours of Fluoroscopic "On Time" to Reach Threshold** at High-Level Dose Rate of 0.2 Gy/min (20 rad/min)	Time to Onset of Effect***
Early transient erythema	2	1.7	0.17	hours
Temporary epilation	3	2.5	0.25	3 wk
Main erythema	6	5.0	0.50	10 d
Permanent epilation	7	5.8	0.58	3 wk
Dry desquamation	10	8.3	0.83	4 wk
Invasive fibrosis	10	8.3	0.83	
Dermal atrophy	11	9.2	0.92	14 wk
Telangiectasis	12	10.0	1.00	52 wk
Moist desquamation	15	12.5	1.25	4 wk
Late erythema	15	12.5	1.25	6-10 wk
Dermal necrosis	18	15.0	1.50	10 wk
Secondary ulceration	20	16.7	1.67	6 wk

* The unit for absorbed dose is the gray (Gy) in the International System of units. One Gy is equivalent to 100 rad in the traditional system of radiation units.
** Time required to deliver the typical threshold dose at the specified dose rate.
*** Time after single irradiation to observation of effect.

Taken from FDA's Avoidance of Serious X-ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures.

Table 3

Adult Effective Doses for Various Interventional Radiology Procedures

Examination	Average Effective Dose (mSv)*	Values Reported in Literature (mSv)
Head and/or neck angiography	5	0.8–19.6
Coronary angiography (diagnostic)	7	2.0–15.8
Coronary percutaneous transluminal angioplasty, stent placement, or radiofrequency ablation	15	6.9–57
Thoracic angiography of pulmonary artery or aorta	5	4.1–9.0
Abdominal angiography or aortography	12	4.0–48.0
Transjugular intrahepatic portosystemic shunt placement	70	20–180
Pelvic vein embolization	60	44–78

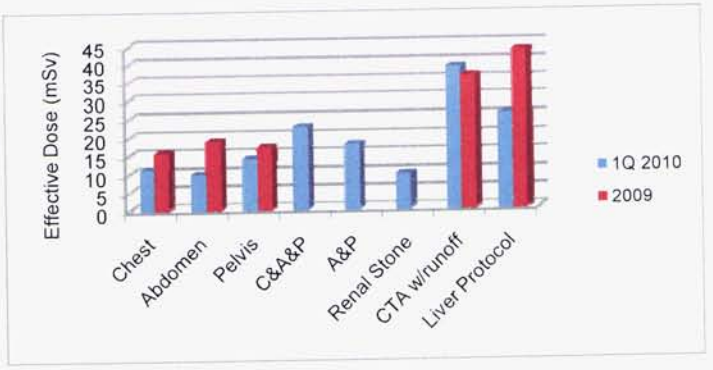
* Values can vary markedly on the basis of the skill of the operator and the difficulty of the procedure.

Taken from Mettler FA, Jr., Huda W, Yoshizumi TT, Mahesh M. Effective doses in radiology and diagnostic nuclear medicine: a catalog. Radiology 2008; 248(1):254-263.

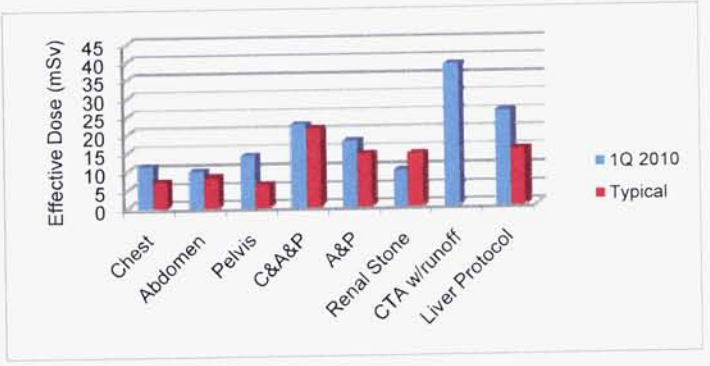
Radiation Safety Committee
CT Radiation Summary
1Q 2010

	Actual 1Q 2010			Typical per Literature			Actual 2009		
Type of CT	**Min**	**Max**	**Average**	**Min**	**Max**	**Average**	**Min**	**Max**	**Average**
Chest	5.7	28.5	11	4	18	7	3.1	46.7	15.4
Abdomen	2.5	16.1	9.7	3.5	25	8	3.8	36.6	18.6
Pelvis	3.9	27.1	13.7	3.3	10	6	3.8	36.6	16.8
C&A&P	8.6	37.4	22.3	10.8	53	21			
A&P	6.4	31.4	17.5	6.8	35	14			
Renal Stone	6	24.9	9.4	6.8	35	14			
CTA w/runoff	14.6	59.9	38.6				15.2	64.3	36.3
Liver Protocol	10.1	46.2	25.6			15	14.7	86.9	43.3

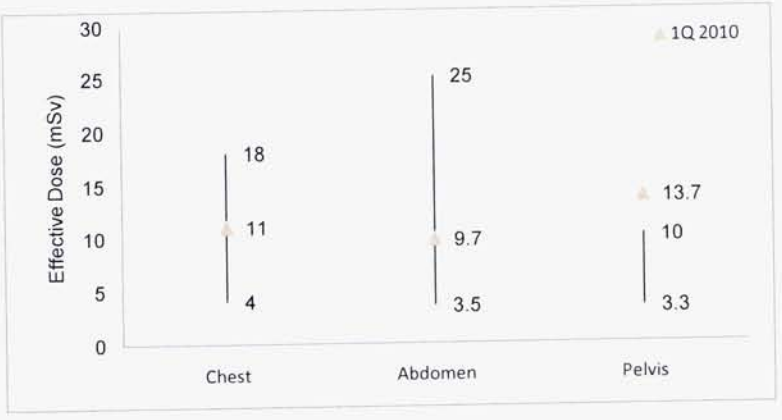
	1Q 2010	2009
Chest	11	15.4
Abdomen	9.7	18.6
Pelvis	13.7	16.8
C&A&P	22.3	
A&P	17.5	
Renal Stone	9.4	
CTA w/runoff	38.6	36.3
Liver Protocol	25.6	43.3



	1Q 2010	Typical
Chest	11	7
Abdomen	9.7	8
Pelvis	13.7	6
C&A&P	22.3	21
A&P	17.5	14
Renal Stone	9.4	14
CTA w/runoff	38.6	
Liver Protocol	25.6	15



	Typical per Literature		Actual 1Q 2010
	Min	**Max**	**Average**
Chest	4	18	11
Abdomen	3.5	25	9.7
Pelvis	3.3	10	13.7



Radiation Safety Committee
Detailed Audit for Jan-Mar 2010
ALARA-Radiation Exposure

1. **Personnel Exposure Records/ALARA Investigational Levels:**

Quarterly ALARA Levels & Annual Limits are expressed in mrem	ALARA Quarterly Investigational Levels		Annual Limits*
	Level I (10% of ¼ annual limits)	Level II (30% of ¼ annual limits)	
Whole Body (WB) Deep Exposure (DDE = Deep Dose Equivalent) (if lead/lead equivalent apron **not** used)	125	375	5,000
Whole Body Effective Dose Equivalent (WB EDE) = 0.3 x DDE (due to use of lead/lead equivalent apron)	125	375	5,000
Lens of Eye Exposure (LDE = Lens Dose Equivalent)	375	1,125	15,000
WB Shallow (Skin) Exposure (SDE = Shallow Dose Equivalent)	1,250	3,750	50,000
Extremity Shallow Exposure (SDE = Shallow Dose Equivalent)	1,250	3,750	50,000
* Annual Occupational Dose Limits for Adults based on NRC Regulations			

A. Radioactive Materials Use:

a) Follow-up on previous quarter's review: x0
- None to report.

b) Exceeded the ALARA Quarterly Investigational Level I (10% of ¼ annual limit): x0
- None to report.

c) Exceeding ALARA Quarterly Investigational Level II (30% of ¼ annual limit): x0
- None to report.

B. Radiographic-Fluoroscopic Use:

a) Follow-up on previous quarter's review: x0
- None to report.

b) Exceeded the ALARA Quarterly Investigational Level I (10% of ¼ annual limit): x2 Total

Exceeded the whole body effective dose equivalent of 125 mrem: x1

1) Badge # 1065, anesthesiologist in the pain clinic exceeded the whole body effective dose equivalent ALARA investigational level I of 125 mrem with a quarterly reading of **212 mrem**, which is only 4.2% of the annual limit. An electronic and written notification was sent to the employee. The RSO reviewed these readings with the employee. This level of exposure is not unusual in areas with frequent C-arm use and the employee's projected annual exposure is expected to be well below annual occupational limits.

Exceeded the lens dose equivalent of 375 mrem: x1

1) Badge # 1065, anesthesiologist in the pain clinic exceeded the lens dose equivalent ALARA investigational level I of 375 mrem with a quarterly reading of **708 mrem**, which is only 4.7% of the annual limit. An electronic and written notification was sent to the employee. The RSO reviewed these readings with the employee. The employee wears leaded glasses during fluoro cases; therefore, his actual dose to his lens is much lower than reported above (i.e., up to 90% reduction). This level of exposure is not unusual in areas with frequent C-arm use and the employee's projected annual exposure is expected to be well below annual occupational limits.

Follow-up: No other action is required at this time. The RSO is will continue to monitor the above employee's quarter's exposure readings and report on next ALARA audit.

c) Exceeding ALARA Quarterly Investigational Level II (30% of ¼ annual limit): x0
- None to report.

Radiation Safety Committee
Detailed Audit for Jan-Mar 2010
ALARA-Radiation Exposure

2. I-125/I-131 Bioassay Results:

Were performed 6-72 hours post handling and each measured uptake was less than or equal to the minimal detectable activity (MDA) of the counting system on the day of counting. Radiopharmaceutical and research use records were reviewed to assure that each use requiring a bioassay had a documented bioassay.

a) Nuclear Medicine: Administration of ≥ 1 mCi in solution or ≥ 10 mCi in capsule form of I-131 as NaI or any problem/issue (e.g., spill, damaged capsule) with I-131 as NaI that may lead to intake even though based on past bioassays and our I-131 as NaI usage, it is unlikely that any staff member exceed 10% of the annual limit on intake (i.e., 5 μCi/year via inhalation with ALI of 50 μCi/year):

- 4 employees (4 bioassays) after 4 NaI administrations (i.e., 10.7-103.0 mCi in capsule form) with MDA of ≤ 0.007 μCi.

b) Research: Use of ≥ 1 mCi in solution of I-125 as NaI or any problem/issue (e.g., spill) with I-125 as NaI that may lead to intake:

- None to report.

Follow-up: None required.

3. Pregnant Radiation Workers:

- None to report.

4. Quarterly Area Monitors Involving Radioactive Materials:

Three areas are monitored with quarterly radiation badges (deep dose equivalent):

			QTR mrem	2010 mrem
a)	NM2	Wall in main hallway outside Nuclear Medicine, i.e., outer wall of hot lab	2	2
b)	NM3	Wall in main hallway outside Nuclear Medicine, i.e., outer wall of hot lab	M	M
c)	RES1	Doorway of research radioactive waste storage room	M	M

The minimal detectable (M) quantity is <1 mrem for x-ray and gamma rays, and <10 mrem for energetic beta particles). The projected 2010 annual readings for all the above areas are expected to be less than 100 mrem/area.

Follow-up: None required.

5. Sanitary Sewer Disposal of Radioactive Material:

- None to report.

6. Radiation Safety Improvements and/or Additional Comments/Problems: Yes x1 If yes, explain below.

- Added links in trending/detailed reports to staff exposure trending reports for employees who exceed ALARA during the year.

Audit performed by: Michael T. Hackett, MS, Radiation Safety Officer

Radiation Safety Committee
Detailed Audit for Jan-Mar 2010
Prostate Brachytherapy

Review of VA Patients being sent out for prostate brachytherapy at a non-VA institution.

1. "Procedure Record" (i.e., non-VA institution's written directive) Review:

Patient #	1	2
Date of prostate brachytherapy	01/19/2010	03/19/2010
Prescription Plan:		
# of I-125 seeds	73	77
Activity per seed in mCi	0.379	0.410
Total activity in mCi	27.64	31.6
Prescribed dose to the prostate in Gy	144	144
Signed by Oncologist	Yes	Yes
Patient Identification Verification:		
# of ID sources used to verify the patient (2 required)	2	2
Radioactive Seed (i.e., I-125) Inventory:		
# of I-125 seeds to the OR	90	90
Total activity received in mCi	34.1	36.9
# of I-125 seeds used	73	77
If # used ≠ # in plan, what % difference	N/A	N/A
Total activity used in mCi	27.64	31.6
# of I-125 seeds returned	17	13
Signed/dated that all seeds accounted for	Yes	Yes
Final Room Survey:		
Background survey in cpm	100	~100
Room survey (after patient leaves) in cpm	100	~100
QMP Review:		
Initialed/dated	Yes	Yes
# of deficiencies noted	0	0

2. "Special Radiation Physics Consult" (i.e., non-VA institution's review of post implant CT) Review:

Patient #	1	2
Date of post prostate brachytherapy CT	03/09/2010	04/21/2010
# of I-125 seeds located	73	77
# of I-125 seeds implanted	73	77
If # located ≠ # implanted, what % difference	N/A	N/A

3. Post Implant CT Review by non-VA institution's Medical Physicist:

Patient #	1	2
# of seeds outside of the treatment volume (TV)	0	2
If seeds located outside of TV, what % of implanted	N/A	2.6%

4. Post Implant CT Review by VA Radiologist:

Patient #	1	2
# of seeds outside of the treatment volume (TV)	0	0
If seeds located outside of TV, what % of implanted	N/A	N/A

5. Medical Review by VA Urologist:

Patient #	1	2
Date of VA Urology follow up appointment	03/30/2010	Pending
Major complications found other than minor, but expected routine complications (e.g., urinary tract infection, mild radiation proctitis, urge urinary incontinence and urinary retention)	No	Pending Urology follow up

Radiation Safety Committee
Detailed Audit for Jan-Mar 2010
Prostate Brachytherapy

6. **Radiation Safety Improvements and/or Additional Comments/Problems:** Yes x1 If yes, explain below.
   - Developed trending report & detailed audit for prostate brachytherapy which included data from 2008-2009.

Audit performed by: Michael T. Hackett, MS, Radiation Safety Officer

Radiation Safety Committee
Trending Report for Jan-Mar 2010
Deficiency Summary

Link to Notable Changes & Updates Trending Report Link to Pending Items Trending Report		Links to	Nucl Med	Research	Rad-Fluoro	ALARA-Rad Exp	Prostate Brachy	Trending Reports	
Click on the highlighted links/tabs below or above for more information concerning these deficiencies (or notable changes & updates/pending items) via the area trending report and/or detailed audits.		Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	*2009 Qtrly Average*	*2009 Total*
Nuclear Medicine									
4. Daily Dose Calibrator (DC) Constancy Checks (2 dose calibrators):									
# of times constancy checks not performed daily if used for pts as required	D	1				1.0	1	*0.3*	*1*
Research									
N/A		N/A				N/A	N/A	*N/A*	*N/A*
Radiographic-Fluoroscopic Use									
1. Patient radiation dose from CT (B152 only):									
D. Low Volume Cases									
(2) Broken down by Procedure Type:		CT PELVIS W/O CONTRAST						*Apr-Jun 2009 CT PELVIS W/O CONTRAST*	
# of these cases reviewed with pt effective dose ≥10 mSv but ≤100 mSv	V	4				N/A	N/A	*22*	*N/A*
(3) Broken down by Procedure Type:		CTA AORTA W/RUNOFF, A-P Region						*Jan-Mar 2009 CTA AORTA W/RUNOFF*	
Average patient effective dose (mSv) for these cases that were reviewed	V	38.6				N/A	N/A	*36.3*	*N/A*
2. Patient radiation dose from Interventional Fluoroscopy (Specials B180):									
# of these cases with dose ≥3 Gy but <10 Gy	D	2				2.0	2	*0.5*	*2*
3. Patient radiation dose from Cardiac Cath (A233 & A235, EP & Cardiac Cath Labs):									
# of these cases with corrected absorbed dose ≥3 Gy but <10 Gy	D	54				54.0	54	*55*	*219*
# of these cases with corrected absorbed dose ≥10 Gy but <15 Gy	D	2				2.0	2	*1*	*2*
# of these cases with corrected absorbed dose ≥15 Gy	D	2				2.0	2	*0*	*0*
# of these cases with effective dose >100 mSv	D	7				7.0	7	*N/A*	*N/A*
ALARA-Radiation Exposure									
1. Personnel Exposure Records/ALARA Investigational Levels (see below):									
B. Radiographic-Fluoroscopic Use:									
b) # of times ALARA Quarterly Investigational Level I (10% of ¼ annual limit) was exceeded	D	2				2.0	2	*0.8*	*3*
Prostate Brachytherapy									
3. Post Implant CT Review by non-VA institution's Medical Physicist:									
# of times implanted seeds found outside of the treatment area	D	1				1.0	1	*1.25*	*5*

D = Discrepancy/Problem Indicator V = Volume Indicator

Radiation Safety Committee
Trending Report for Jan-Mar 2010
Notable Changes & Updates

Link to Deficiency Summary Trending Report

Link to Pending Items Trending Report

Click on the highlighted links/tabs below or above for more information concerning these notable changes & updates (or deficiencies/pending items) via the area trending report and/or detailed audits.

		Links to	Nucl Med	Research	Rad-Fluoro	ALARA-Rad Exp	Prostate Brachy	Trending Reports	
		Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	*2009 Qtrly Average*	*2009 Total*
Nuclear Medicine									
21. Radiation Safety Improvements and/or Additional Comments/Problems:									
Updated software for uptake/well system to include ability to measure & quantify internal organ burden after a radiological event.	N/A	in Feb				N/A	in Feb	*N/A*	*N/A*
Fabricated two new replacement lead containers with chained clips on lead tops for use with two Co-57 spot markers.	N/A	in Feb				N/A	in Feb	*N/A*	*N/A*
VA Police performed the annual Physical Security Survey for Nuclear Medicine - no violations found.	N/A	in Feb				N/A	in Feb	*N/A*	*N/A*
Research									
16. Radiation Safety Improvements and/or Additional Comments/Problems:									
Replaced current volume labeling of vial with index card located in vial's re-sealable bag's document pouch.	N/A	in Mar				N/A	in Mar	*N/A*	*N/A*
Radiographic-Fluoroscopic Use									
1. Patient radiation dose from CT (B152 only):									
B. High Volume Cases (different procedures reviewed each qtr):		CT CHEST W/O CONTRAST						*Jan-Mar 2009 CT CHEST W/O CONTRAST*	
(1) Broken down by Procedure Type:						N/A	N/A		*N/A*
Average patient effective dose (mSv) for these cases that were reviewed	V	11.0				N/A	N/A	*15.4*	*N/A*
D. Low Volume Cases (different procedures reviewed each qtr):		CT ABDOMEN W/O CONTRAST						*Apr-Jun 2009 CT ABDOMEN W/O CONTRAST*	
(1) Broken down by Procedure Type:						N/A	N/A		*N/A*
Average patient effective dose (mSv) for these cases that were reviewed	V	9.7				N/A	N/A	*18.6*	*N/A*
(2) Broken down by Procedure Type:		CT PELVIS W/O CONTRAST						*Apr-Jun 2009 CT PELVIS W/O CONTRAST*	
Average patient effective dose (mSv) for these cases that were reviewed	V	13.7				N/A	N/A	*16.8*	*N/A*
(4) Broken down by Procedure Type:		CT ABD W&W/O CONTRAST LIVER PROTOCOL						*Jan-Mar 2009 CT ABD W&W/O CONTRAST LIVER PROTOCOL*	
Average patient effective dose (mSv) for these cases that were reviewed	V	25.6				N/A	N/A	*43.3*	*N/A*
5. Radiation Safety Improvements and/or Additional Comments/Problems:									
Changed trending audit to display only quarterly data (i.e., no monthly breakdown) to be consistent with other trending audits.	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*
Added CT Radiation Summary Charts as part of CT Review (item 1).	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*
Added monitoring of effective doses as part of the Cardiac Cath review (item 3) and a related reference (Table 3).	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*
Changed breakdown of Cardiac Cath review (item 3) from by room to by procedure type (Diagnostic, Interventional, Electrophysiology).	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*
ALARA-Radiation Exposure									
6. Radiation Safety Improvements and/or Additional Comments/Problems:									
Added links in trending/detailed reports to staff exposure trending reports for employees who exceed ALARA during the year.	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*
Prostate Brachytherapy									
6. Radiation Safety Improvements and/or Additional Comments/Problems:									
Developed trending report & detailed audit for prostate brachytherapy which included data from 2008-2009.	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*

D = Discrepancy/Problem Indicator V = Volume Indicator

Radiation Safety Committee
Trending Report for Jan-Mar 2010
Pending Items

Link to Deficiency Summary Trending Report Link to Notable Changes & Updates Trending Report		Links to	Nucl Med	Research	Rad-Fluoro	ALARA-Rad Exp	Prostate Brachy	Trending Reports	
Click on the highlighted links/tabs below or above for more information concerning these pending items (or deficiencies/notable changes & updates) via the area trending report and/or detailed audits.		Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	*2009 Qtrly Average*	*2009 Total*
Nuclear Medicine									
N/A		N/A				N/A	N/A	*N/A*	*N/A*
Research									
N/A		N/A				N/A	N/A	*N/A*	*N/A*
Radiographic-Fluoroscopic Use									
3. Patient radiation dose from Cardiac Cath (A233 & A235, EP & Cardiac Cath Labs):									
# of these cases with corrected absorbed dose ≥10 Gy but <15 Gy	D	2 Pt Reviews Pending				N/A	N/A	*N/A*	*N/A*
# of these cases with corrected absorbed dose ≥15 Gy	D	2 Pt Reviews Pending				N/A	N/A	*N/A*	*N/A*
ALARA-Radiation Exposure									
N/A		N/A				N/A	N/A	*N/A*	*N/A*
Prostate Brachytherapy									
5. Medical Review by VA Urologist:									
# of times major complications found other than minor, but expected routine complications	D	1 Pt Review Pending				N/A	N/A	*N/A*	*N/A*

D = Discrepancy/Problem Indicator V = Volume Indicator

Radiation Safety Committee
Trending Report for Jan-Mar 2010
Nuclear Medicine

Links to

Deficiency Summary Trending Report
Notable Changes & Updates Trending Report
Pending Items Trending Report

Click on the links to the right for the detailed audits of Nuclear Medicine for 2010 or the Trending Report for 2009 (on far right) which includes links to 2009 detailed audits.		Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	2009 Qtrly Average	2009 Total
1. Daily Radiation Surveys:									
# of times surveys not performed daily as required	D	0				0.0	0	0.0	0
# of times surveys greater than trigger level	D	0				0.0	0	1.3	5
By area: Hot Lab	D	0				0.0	0	0.0	0
Imaging Room	D	0				0.0	0	0.8	3
Injection Room	D	0				0.0	0	0.5	2
# of times appropriate action was not taken to decrease levels below trigger level	D	N/A				N/A	N/A	0.0	0
2. Weekly Radiation Wipes:									
# of times wipes not performed weekly as required	D	0				0.0	0	0.0	0
# of times wipes greater than trigger level	D	0				0.0	0	1.0	4
By area: Hot Lab	D	0				0.0	0	0.5	2
Imaging Room	D	0				0.0	0	0.5	2
Injection Room	D	0				0.0	0	0.0	0
# of times appropriate action was not taken to decrease levels below trigger level	D	N/A				N/A	N/A	0.0	0
3. Item Currently Not Tracked (Mo-99/Tc-99m Assays - discontinued use in June 2008 due to revised USP <797>)	N/A	N/A				N/A	N/A	N/A	N/A
4. Daily Dose Calibrator (DC) Constancy Checks (2 dose calibrators):									
# of times constancy checks not performed daily if used for pts as required	D	1				1.0	1	0.3	1
# of times quarterly full constancy check not performed	D	0				0.0	0	0.0	0
# of times constancy checks not within limits	D	0				0.0	0	0.0	0
5. Quarterly Dose Calibrator Linearity Checks (2 dose calibrators):									
# of times linearity checks not performed quarterly/post repair as required	D	0				0.0	0	0.0	0
# of times linearity checks not within limits	D	0				0.0	0	0.0	0
6. Annual Dose Calibrator Accuracy Checks (2 dose calibrators):									
# of times accuracy checks not performed annually (Sep)/post repair as required	D	N/A				N/A	N/A	0.0	0
# of times accuracy checks not within limits	D	N/A				N/A	N/A	0.0	0
7. Dose Calibrator Geometry Checks (2 dose calibrators):									
# of times geometry checks not performed post repair as required	D	N/A				N/A	N/A	N/A	N/A
# of times geometry checks not within limits	D	N/A				N/A	N/A	N/A	N/A
8. Daily Thyroid Probe/Well & Multi-Well Counters Constancy Checks:									
# of times constancy checks not performed daily (i.e., when used) as required	D	0				0.0	0	0.0	0
# of times constancy checks not within limits	D	0				0.0	0	0.0	0
9. Quarterly Thyroid Probe/Well Counter & Multi-Well Counter Checks:									
# of times quarterly checks not performed as required	D	0				0.0	0	0.0	0
# of times quarterly checks not within limits	D	0				0.0	0	0.0	0
10. Monthly Xenon Machine Quality Control Checks:									
# of times monthly/quarterly quality control checks not performed as required	D	0				0.0	0	0.0	0
# of times quality control checks not within limits	D	0				0.0	0	0.0	0
11. Semi-Annual Air Flow Measurements (AFM) & Xenon Spill Clearance Time Calculations/ Annual Fume Hood Certification									
# of times semi-annual (Jun & Dec) AFM not performed as required	D	N/A				N/A	N/A	0.0	0
# of times imaging room & hot lab found not to be under negative pressure based on above AFM	D	N/A				N/A	N/A	0.0	0
# of times smoke test did not confirm that the room was under negative pressure	D	N/A				N/A	N/A	0.0	0
# of times Xenon spill clearance times not calculated and not posted for above AFM	D	N/A				N/A	N/A	0.0	0
# of times annual (Feb) fume hood certification not performed as required	D	0				0.0	0	0.0	0
# of times fume hood sash level not noted for above certification	D	0				0.0	0	0.0	0

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12. Annual Survey Meter Calibrations:									
# of times annual calibration (Mar)/post repair not performed as required	D	0				0.0	0	0.0	0
# of survey meters calibrated	V	6				6.0	6	6.0	6
13. Quarterly/Annual Radionuclide Sealed Source Inventory:									
# of times quarterly inventories not performed as required	D	0				0.0	0	0.0	0
# of unaccounted for sealed sources	D	0				0.0	0	0.0	0
# of sealed sources on inventory	V	139				139.0	N/A	137.3	N/A
# of sealed sources added to inventory during the quarter (may/may not be in above total due to when received)	V	2				2.0	2	0.0	0
# of sealed sources removed from inventory during the quarter (may/may not be in above total due to when shipped)	V	0				0.0	0	0.3	1
# of times monthly check of Cs-137 calibration source not performed	D	0				0.0	0	0.0	0
# of times annual (Mar) NHPP sealed source verification not performed as required	D	0				N/A	0	N/A	0
# of sealed sources on NHPP inventory	V	2				N/A	2	N/A	2
14. Semi-Annual Radionuclide Sealed Source Leak Testing:									
# of times semi-annual (Jan & Jul) leak test not performed as required	D	0				0.0	0	0.0	0
# of sealed sources leak tested	V	3				3.0	N/A	3.5	N/A
# of leak tests with leakage detected above required limits	D	0				0.0	0	0.0	0
15. Reportable or Recordable Events/Incidents:									
# of times a reportable or recordable event/incident occurred	D	0				0.0	0	0.0	0
16. Reported Radioactive Spills:									
# of times a reported radioactive spill occurred	D	0				0.0	0	0.3	1
# of times appropriate action to the spill was not taken	D	N/A				N/A	N/A	0.0	0
17. Quarterly Review of In-coming Radionuclide Receiving Records:									
# of times receiving records were missing pertinent info (e.g., survey/wipe results)	D	0				0.0	0	0.3	1
# of times package receiving problems noted (e.g., contamination, wrong material)	D	0				0.0	0	1.5	6
Total # of in-coming shipments (note some non-Tc-99m may be included within Tc-99m shipments - see detailed audit)	V	214				214.0	214	209.0	836
# of in-coming shipments noted above that were from the local radiopharmacy	V	196				196.0	196	178.8	715
Total activity in mCi contained in the above shipments for: Co-57	V	0.1				0.1	0.1	0.0	0.0
Ga-67	V	10.1				10.1	10.1	12.0	47.9
I-131 (in capsule)	V	251.0				251.0	251.0	134.8	539.2
In-111	V	7.2				7.2	7.2	7.6	30.4
Tc-99m	V	23,440.6				23,440.6	23,440.6	24,190.7	96,762.9
Tl-201	V	39.7				39.7	39.7	283.7	1134.7
Xe-133	V	548.3				548.3	548.3	600.8	2,403.3
18. Quarterly Review of Out-going Radionuclide/Return Package Records:									
# of times out-going records were missing pertinent info (e.g., survey/wipe results)	D	0				0.0	0	0.0	0
# of times out-going package problems noted (e.g., contamination)	D	0				0.0	0	0.0	0
# of out-coming shipments	V	196				196.0	196	177.3	709
# of out-coming shipments noted above that were return packages to local radiopharmacy	V	196				196.0	196	177.0	708
# of out-coming shipments noted above that were sealed sources returns	V	0				0.0	0	0.3	1
# of in-coming shipments from local radiopharmacy that did not have out-going documentation	D	0				0.0	0	1.8	7
19. Written Directive (WD) Audits for Nuclear Medicine:									
# of total written directives used for the quarter	V	8				8.0	8	5.0	20
# of written directives that were for I-131 whole body imaging	V	4				4.0	4	3.0	12
# of written directives that were for I-131 therapy for hyperthyroidism	V	2				2.0	2	1.3	5
# of written directives that were for I-131 therapy for thyroid cancer	V	2				2.0	2	0.8	3
# of problems noted	D	0				0.0	0	0.0	0

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20. Training (Include all staff if dealing with clinical use of radionuclides.):									
Total # of radiation safety training hours provided	V	16.00				16.00	16.00	56.49	225.95
# radiation safety training hours provided to Nuclear Medicine staff	V	13.50				13.50	13.50	5.75	23.00
# radiation safety training hours provided to AOD staff	V	0.00				0.00	0.00	1.50	6.00
# radiation safety training hours provided to EMS staff	V	1.00				1.00	1.00	24.63	98.50
# radiation safety training hours provided to VA Police staff	V	0.00				0.00	0.00	8.75	35.00
# radiation safety training hours provided to Warehouse staff	V	0.00				0.00	0.00	2.75	11.00
# radiation safety training hours provided as FYI training (e.g., Radiation Safety, Safety Office staff)	V	1.50				1.50	1.50	13.11	52.45
# of times DOT HAZMAT training not done as required (i.e., new staff w/i 90 days; 3yr refresher due by 9/21/10 - last done 9/21/07)	D	N/A				N/A	N/A	N/A	N/A
21. Radiation Safety Improvements and/or Additional Comments/Problems:									
Updated software for uptake/well system to include ability to measure & quantify internal organ burden after a radiological event.	N/A	in Feb				N/A	in Feb	N/A	N/A
Fabricated two new replacement lead containers with chained clips on lead tops for use with two Co-57 spot markers.	N/A	in Feb				N/A	in Feb	N/A	N/A
VA Police performed the annual Physical Security Survey for Nuclear Medicine - no violations found.	N/A	in Feb				N/A	in Feb	N/A	N/A

D = Discrepancy/Problem Indicator V = Volume Indicator

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1. Monthly Radiation Surveys/Wipes of Core Labs, Waste, Common Areas done by RSO:									
# of times surveys/wipes not performed monthly as required	D	0				0.0	0	*0.0*	*0*
# of times surveys/wipes greater than trigger level	D	0				0.0	0	*0.0*	*0*
# of times appropriate action was not taken to decrease levels below trigger level	D	N/A				N/A	N/A	*N/A*	*N/A*
2. Annual Radiation Surveys/Wipes of each Authorized User Lab/Room done by RSO:									
# of times surveys/wipes not performed annually (Dec) as required	D	N/A				N/A	N/A	*N/A*	*0*
# of times surveys/wipes greater than trigger level	D	N/A				N/A	N/A	*N/A*	*0*
# of times appropriate action was not taken to decrease levels below trigger level	D	N/A				N/A	N/A	*N/A*	*N/A*
# of rooms monitored	V	N/A				N/A	N/A	*N/A*	*11*
# of Authorized Users	V	N/A				N/A	N/A	*N/A*	*10*
3. Quarterly Record Audit of Weekly Radiation Wipes Performed by each Authorized User Labs:									
# of times wipes not performed weekly as required	D	0				0.0	0	*0.0*	*0*
# of times wipes greater than trigger level	D	0				0.0	0	*0.0*	*0*
# of times appropriate action was not taken to decrease levels below trigger level	D	N/A				N/A	N/A	*N/A*	*N/A*
# of rooms monitored	V	13				13.0	N/A	*12.5*	*N/A*
# of labs Authorized Users	V	10				10.0	N/A	*9.0*	*N/A*
4. Quarterly/Annual Radionuclide Sealed Source Inventory of Labs and Core Labs done by RSO:									
# of times quarterly inventories not performed as required	D	0				0.0	0	*0.0*	*0*
# of unaccounted for sealed sources	D	0				0.0	0	*0.0*	*0*
# of sealed sources on inventory	V	17				17.0	N/A	*17.0*	*N/A*
# of sealed sources added to inventory during the quarter (may/may not be in above total due to when received)	V	0				0.0	0	*0.0*	*0*
# of sealed sources removed from inventory during the quarter (may/may not be in above total due to when shipped)	V	0				0.0	0	*0.0*	*0*
# of times annual (Mar) NHPP sealed source verification not performed as required	D	0				N/A	0	*N/A*	*0*
# of sealed sources on NHPP inventory	V	2				N/A	2	*N/A*	*2*
5. Semi-Annual Radionuclide Sealed Source Leak Testing by RSO:									
# of times semi-annual (Jan & Jul) leak test not performed as required	D	0				0.0	0	*0.0*	*0*
# of sealed sources leak tested	V	2				2.0	N/A	*2.0*	*N/A*
# of leak tests with leakage detected above required limits	D	0				0.0	0	*0.0*	*0*
6. Quarterly Radionuclide (Unsealed) Inventory of each Authorized User Lab done by RSO:									
# of times quarterly inventories (based on first date of quarters possession) not performed as required	D	0				0.0	0	*0.0*	*0*
# of unaccounted for unsealed sources	D	0				0.0	0	*0.0*	*0*
# of times Authorized User was over their possession limits	D	0				0.0	0	*0.0*	*0*
# of Authorized Users	V	10				10.0	N/A	*9.0*	*N/A*
7. Reported Radioactive Spills:									
# of times a reported radioactive spill occurred	D	0				0.0	0	*0.0*	*0*
# of times appropriate action to the spill was not taken	D	N/A				N/A	N/A	*N/A*	*N/A*
8. Authorized User Lab Closings:									
# of labs closed out (i.e., monitored and released for general use)	V	0				0.0	0	*0.3*	*1*
9. Annual Survey Meter Calibrations:									
# of times annual calibration (Mar)/post repair not performed as required	D	0				0.0	0	*0.0*	*0*
# of survey meters calibrated	V	5				5.0	5	*2.0*	*4*
10. Annual Beta Counter (2) Quench Curve and Gamma Counter (2) Calibration:									
# of times Quench Curve and Gamma Calibration not performed annually (Jan)/post repair as required	D	0				0.0	0	*0.0*	*0*

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11. Monthly Beta Counter (2) Normalization, Chi-Square, and Constancy Checks and Gamma Counter (2) Peak, % Resolution, Chi-Square, Constancy, and Efficiency Checks:									
# of times above checks not performed monthly as required	D	0				0.0	0	0.0	0
# of times above checks not within limits	D	0				0.0	0	0.0	0
12. Authorized User Approval by the RSC:									
# of authorized user approvals/re-approvals by the RSC	V	1				1.0	1	0.5	2
13. Quarterly Review of In-coming Radionuclide Receiving Records:									
# of times shipments received that were not pre-approved by the RSO	D	0				0.0	0	0.0	0
# of times receiving records were missing pertinent info (e.g., survey/wipe results)	D	0				0.0	0	0.0	0
# of times package receiving problems noted (e.g., contamination, wrong material)	D	0				0.0	0	0.0	0
Total # of in-coming shipments	V	1				1.0	1	1.8	7
# of C-14 in-coming shipments	V	0				0.0	0	0.0	0
Total C-14 activity in mCi contained in the above shipments	V	0.00				0.00	0.00	0.00	0.00
# of Cr-51 in-coming shipments	V	0				0.0	0	0.0	0
Total Cr-51 activity in mCi contained in the above shipments	V	0.00				0.00	0.00	0.00	0.00
# of H-3 in-coming shipments	V	0				0.0	0	0.3	1
Total H-3 activity in mCi contained in the above shipments	V	0.00				0.00	0.00	1.25	5.00
# of I-125 in-coming shipments	V	0				0.0	0	0.5	2
Total P-32 activity in mCi contained in the above shipments	V	0.00				0.00	0.00	1.49	5.95
# of P-32 in-coming shipments	V	1				1.0	1	1.0	4
Total P-32 activity in mCi contained in the above shipments	V	0.37				0.37	0.37	0.57	2.26
# of S-35 in-coming shipments	V	0				0.0	0	0.0	0
Total S-35 activity in mCi contained in the above shipments	V	0.00				0.00	0.00	0.00	0.00
14. Quarterly Review of Out-going Radionuclide/Return Package Records:									
# of times out-going records were missing pertinent info (e.g., survey/wipe results)	D	N/A				N/A	N/A	N/A	N/A
# of times out-going package problems noted (e.g., contamination)	D	N/A				N/A	N/A	N/A	N/A
# of out-coming shipments	V	0				0.0	0	0.0	0
15. Training (Include all staff if dealing with research use of radionuclides.): See Nuclear Medicine audits for support staff (e.g., EMS, Police, etc.)									
Total # of radiation safety training hours provided	V	9.25				9.25	9.25	10.92	43.67
# radiation safety training hours provided to Research staff	V	9.25				9.25	9.25	10.17	40.67
# radiation safety training hours provided as FYI training (e.g., Radiation Safety, Safety Office staff)	V	0.00				0.00	0.00	0.75	3.00
16. Radiation Safety Improvements and/or Additional Comments/Problems:									
Replaced current volume labeling of vial with index card located in vial's re-sealable bag's document pouch.	N/A	in Mar				N/A	in Mar	N/A	N/A

D = Discrepancy/Problem Indicator V = Volume Indicator

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1. Patient radiation dose from CT (B152 only): **See reference tables/links at end of this audit related to effective doses.**									
Total # of CT exams	V	2976				2976.0	2976	3045.5	12182
Total # of CT procedures	V	55				55.0	55	59.3	70
Average # exams/procedure (note: patient may have multiple procedures; dose may reflect all exams done)	V	54.1				54.1	54.1	51.4	174.0
A. Item Currently Not Tracked (Interventional CT Exams - 2009: 100% initial monitoring, 2010: discontinue qtrly monitoring)	V	N/A				N/A	N/A	38.3	153
B. High Volume Cases (different procedures reviewed each qtr - at least 2 per qtr):		CT CHEST W/O CONTRAST						Jan-Mar 2009 CT CHEST W/O CONTRAST	
(1) Broken down by Procedure Type:						N/A	N/A		N/A
# of CT cases (case = 1 or more exams) documented as being performed	V	284				N/A	N/A	N/A	N/A
# of CT exams per case	V	1				N/A	N/A	N/A	N/A
% of total # of CT exams (i.e., based on # of exams not cases)	V	10%				N/A	N/A	11%	N/A
# of these cases reviewed (i.e., 10% w/ 30 cases minimum) for ~ pt radiation dose (i.e., DLP)	V	30				N/A	N/A	32	N/A
Average effective dose (mSv) for these cases that were reviewed	V	11.0				N/A	N/A	15.4	N/A
# of these cases reviewed with effective dose ≥10 mSv but ≤100 mSv	V	16				N/A	N/A	19	N/A
% of cases reviewed with effective dose ≥10 mSv but ≤100 mSv compared to total cases reviewed	V	53%				N/A	N/A	59%	N/A
# of these cases reviewed with effective dose >100 mSv	D	0				N/A	N/A	0	N/A
(2) Broken down by Procedure Type:		CT ABD & PELVIS W/O CONTRAST							
# of CT cases (case = 1 or more exams) documented as being performed	V	238				N/A	N/A	N/A	N/A
# of CT exams per case	V	2				N/A	N/A	N/A	N/A
% of total # of CT exams (i.e., based on # of exams not cases)	V	16%				N/A	N/A	N/A	N/A
# of these cases reviewed (i.e., 10% w/ 30 cases minimum) for ~ pt radiation dose (i.e., DLP)	V	30				N/A	N/A	N/A	N/A
Average effective dose (mSv) for these cases that were reviewed	V	17.5				N/A	N/A	N/A	N/A
# of these cases reviewed with effective dose ≥10 mSv but ≤100 mSv	V	24				N/A	N/A	N/A	N/A
% of cases reviewed with effective dose ≥10 mSv but ≤100 mSv compared to total cases reviewed	V	80%				N/A	N/A	N/A	N/A
# of these cases reviewed with effective dose >100 mSv	D	0				N/A	N/A	N/A	N/A
C. Average Volume Cases (different procedures reviewed each qtr- at least 2 per qtr):		CT CHEST, ABD & PELVIS W/O CONTRAST							
(1) Broken down by Procedure Type:						N/A	N/A	N/A	N/A
# of CT cases (case = 1 or more exams) documented as being performed	V	59				N/A	N/A	N/A	N/A
# of CT exams per case	V	3				N/A	N/A	N/A	N/A
% of total # of CT exams (i.e., based on # of exams not cases)	V	6%				N/A	N/A	N/A	N/A
# of these cases reviewed (i.e., 30 cases if possible) for ~ pt radiation dose (i.e., DLP)	V	30				N/A	N/A	N/A	N/A
Average effective dose (mSv) for these cases that were reviewed	V	22.3				N/A	N/A	N/A	N/A
# of these cases reviewed with effective dose ≥10 mSv but ≤100 mSv	V	25				N/A	N/A	N/A	N/A
% of cases reviewed with effective dose ≥10 mSv but ≤100 mSv compared to total cases reviewed	V	83%				N/A	N/A	N/A	N/A
# of these cases reviewed with effective dose >100 mSv	D	0				N/A	N/A	N/A	N/A

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(2) Broken down by Procedure Type:		CT ABD & PELVIS W/O CONTRAST Renal Stone							
# of CT cases (case = 1 or more exams) documented as being performed	V	79				N/A	N/A	N/A	N/A
# of CT exams per case	V	2				N/A	N/A	N/A	N/A
% of total # of CT exams (i.e., based on # of exams not cases)	V	5%				N/A	N/A	N/A	N/A
# of these cases reviewed (i.e., 30 cases if possible) for ~ pt radiation dose (i.e., DLP)	V	30				N/A	N/A	N/A	N/A
Average effective dose (mSv) for these cases that were reviewed	V	9.4				N/A	N/A	N/A	N/A
# of these cases reviewed with effective dose ≥10 mSv but ≤100 mSv	V	7				N/A	N/A	N/A	N/A
% of cases reviewed with effective dose ≥10 mSv but ≤100 mSv compared to total cases reviewed	V	23%				N/A	N/A	N/A	N/A
# of these cases reviewed with effective dose >100 mSv	D	0				N/A	N/A	N/A	N/A
D. Low Volume Cases (different procedures reviewed each qtr - at least 2 per qtr):		CT ABDOMEN W/O CONTRAST						Apr-Jun 2009 CT ABDOMEN W/O CONTRAST	
(1) Broken down by Procedure Type:						N/A	N/A		N/A
# of CT cases (case = 1 or more exams) documented as being performed	V	22				N/A	N/A	N/A	N/A
# of CT exams per case	V	1				N/A	N/A	N/A	N/A
% of total # of CT exams (i.e., based on # of exams not cases)	V	0.7%				N/A	N/A	10%	N/A
# of these cases reviewed (i.e., all cases if possible) for ~ pt radiation dose (i.e., DLP)	V	21				N/A	N/A	32	N/A
Average effective dose (mSv) for these cases that were reviewed	V	9.7				N/A	N/A	18.6	N/A
# of these cases reviewed with effective dose ≥10 mSv but ≤100 mSv	V	12				N/A	N/A	24	N/A
% of cases reviewed with effective dose ≥10 mSv but ≤100 mSv compared to total cases reviewed	V	57%				N/A	N/A	75%	N/A
# of these cases reviewed with effective dose >100 mSv	D	0				N/A	N/A	0	N/A
(2) Broken down by Procedure Type:		CT PELVIS W/O CONTRAST						Apr-Jun 2009 CT PELVIS W/O CONTRAST	
# of CT cases (case = 1 or more exams) documented as being performed	V	11				N/A	N/A	N/A	N/A
# of CT exams per case	V	1				N/A	N/A	N/A	N/A
% of total # of CT exams (i.e., based on # of exams not cases)	V	0.4%				N/A	N/A	9%	N/A
# of these cases reviewed (i.e., all cases if possible) for ~ pt radiation dose (i.e., DLP)	V	9				N/A	N/A	32	N/A
Average effective dose (mSv) for these cases that were reviewed	V	13.7				N/A	N/A	16.8	N/A
# of these cases reviewed with effective dose ≥10 mSv but ≤100 mSv	V	4				N/A	N/A	22	N/A
% of cases reviewed with effective dose ≥10 mSv but ≤100 mSv compared to total cases reviewed	V	44%				N/A	N/A	69%	N/A
# of these cases reviewed with effective dose >100 mSv	D	0				N/A	N/A	0	N/A
(3) Broken down by Procedure Type:		CTA AORTA W/RUNOFF A-P Region						Jan-Mar 2009 CTA AORTA W/RUNOFF	
# of CT cases (case = 1 or more exams) documented as being performed	V	22				N/A	N/A	N/A	N/A
# of CT exams per case	V	1				N/A	N/A	N/A	N/A
% of total # of CT exams (i.e., based on # of exams not cases)	V	0.7%				N/A	N/A	2%	N/A
# of these cases reviewed (i.e., all cases if possible) for ~ pt radiation dose (i.e., DLP)	V	18				N/A	N/A	30	N/A
Average effective dose (mSv) for these cases that were reviewed	V	38.6				N/A	N/A	36.3	N/A
# of these cases reviewed with effective dose ≥10 mSv but ≤100 mSv	V	18				N/A	N/A	30	N/A
% of cases reviewed with effective dose ≥10 mSv but ≤100 mSv compared to total cases reviewed	V	100%				N/A	N/A	100%	N/A
# of these cases reviewed with effective dose >100 mSv	D	0				N/A	N/A	0	N/A

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		Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	2009 Qtrly Average	2009 Total
(4) Broken down by Procedure Type:		CT ABD W&W/O CONTRAST LIVER PROTOCOL						Jan-Mar 2009 CT ABD W&W/O CONTRAST LIVER PROTOCOL	
# of CT cases (case = 1 or more exams) documented as being performed	V	7				N/A	N/A	N/A	N/A
# of CT exams per case	V	1				N/A	N/A	N/A	N/A
% of total # of CT exams (i.e., based on # of exams not cases)	V	0.2%				N/A	N/A	0.4%	N/A
# of these cases reviewed (i.e., all cases if possible) for ~ pt radiation dose (i.e., DLP)	V	7				N/A	N/A	11	N/A
Average effective dose (mSv) for these cases that were reviewed	V	25.6				N/A	N/A	43.3	N/A
# of these cases reviewed with effective dose ≥10 mSv but ≤100 mSv	V	7				N/A	N/A	11	N/A
% of cases reviewed with effective dose ≥10 mSv but ≤100 mSv compared to total cases reviewed	V	100%				N/A	N/A	100%	N/A
# of these cases reviewed with effective dose >100 mSv	D	0				N/A	N/A	0	N/A
2. Patient radiation dose from Interventional Fluoroscopy (Specials B180):									
See reference table/link at end of this audit related to patient skin doses.									
# of Specials cases with documented absorbed dose (i.e., air kerma & assumes no movement of x-ray tube & pt)	V	87				87.0	87	85.0	340
Average fluoro time (min) for these cases	V	11.1				11.1	11.1	6.3	6.3
Average absorbed dose (Gy) for these cases	V	0.5				0.5	0.5	0.3	0.3
# of these cases with absorbed dose ≥3 Gy but <10 Gy	D	2				2.0	2	0.5	2
% of cases with absorbed dose ≥3 Gy but <10 Gy compared to total # of cases	D	2.3%				2.3%	2.3%	0.6%	0.6%
# of these cases with absorbed dose ≥10 Gy but <15 Gy	D	0				0.0	0	0	0
% of cases with absorbed dose ≥10 Gy but <15 Gy compared to total # of cases	D	0.0%				0.0%	0.0%	0.0%	0.0%
# of these cases with absorbed dose ≥15 Gy	D	0				0.0	0	0	0
3. Patient radiation dose from Cardiac Cath (A233 & A235, EP & Cardiac Cath Labs):									
See reference tables/links at end of this audit related to patient skin and effective doses.									
# of Cardiac Cath cases with documented absorbed dose (i.e., air kerma & assumes no movement of x-ray tube & pt)	V	214				214.0	214	211	842
Average fluoro time (min) for these cases	V	15.7				15.7	15.7	15.6	15.6
Average corrected (i.e., corrected for air kerma overestimation) dose (Gy) for these cases	V	2.2				2.2	2.2	2.2	2.2
# of these cases with corrected absorbed dose ≥3 Gy but <10 Gy	D	54				54.0	54	55	219
% of cases with corrected absorbed dose ≥3 Gy but <10 Gy compared to total # of cases	D	25%				25%	25%	26%	26%
# of these cases with corrected absorbed dose ≥10 Gy but <15 Gy	D	2				2.0	2	1	2
		2 Pt Reviews Pending							
% of cases with corrected absorbed dose ≥10 Gy but <15 Gy compared to total # of cases	D	0.9%				0.9%	0.9%	0.2%	0.2%
# of these cases with corrected absorbed dose ≥15 Gy	D	2				2.0	2	0	0
		2 Pt Reviews Pending							
% of cases with corrected absorbed dose ≥15 Gy compared to total # of cases	D	0.9%				0.9%	0.9%	0.0%	0.0%
Average effective dose (mSv) for these cases	V	30.6				30.6	30.6	N/A	N/A
# of these cases with effective dose ≥10 mSv but ≤100 mSv	V	172				172.0	172	N/A	N/A
% of cases with effective dose ≥10 mSv but ≤100 mSv compared to total cases	V	80%				80%	80%	N/A	N/A
# of these cases with effective dose >100 mSv	D	7				7.0	7	N/A	N/A
% of cases with effective dose >100 mSv compared to total cases	D	3.3%				3.3%	3.3%	N/A	N/A

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A. Broken down by Procedure Type - Diagnostic:									
# of Cardiac Cath cases with documented absorbed dose (i.e., air kerma & assumes no movement of x-ray tube & pt)	V	94				94.0	94	N/A	N/A
Average fluoro time (min) for these cases	V	8.5				8.5	8.5	N/A	N/A
Average corrected (i.e., corrected for air kerma overestimation) dose (Gy) for these cases	V	1.5				1.5	1.5	N/A	N/A
# of these cases with corrected absorbed dose ≥3 Gy but <10 Gy	D	8				8.0	8	N/A	N/A
% of cases with corrected absorbed dose ≥3 Gy but <10 Gy compared to total # of cases	D	9%				9%	9%	N/A	N/A
# of these cases with corrected absorbed dose ≥10 Gy but <15 Gy	D	0				0.0	0	N/A	N/A
% of cases with corrected absorbed dose ≥10 Gy but <15 Gy compared to total # of cases	D	0.0%				0.0%	0.0%	N/A	N/A
# of these cases with corrected absorbed dose ≥15 Gy	D	0				0.0	0	N/A	N/A
% of cases with corrected absorbed dose ≥15 Gy compared to total # of cases	D	0.0%				0.0%	0.0%	N/A	N/A
Average effective dose (mSv) for these cases	V	21.3				21.3	21.3	N/A	N/A
# of these cases with effective dose ≥10 mSv but ≤100 mSv	V	76				76.0	76	N/A	N/A
% of cases with effective dose ≥10 mSv but ≤100 mSv compared to total cases	V	81%				81%	81%	N/A	N/A
# of these cases with effective dose >100 mSv	D	1				1.0	1	N/A	N/A
% of cases with effective dose >100 mSv compared to total cases	D	1.1%				1.1%	1.1%	N/A	N/A
B. Broken down by Procedure Type - Interventional:									
# of Cardiac Cath cases with documented absorbed dose (i.e., air kerma & assumes no movement of x-ray tube & pt)	V	76				76.0	76	N/A	N/A
Average fluoro time (min) for these cases	V	23.5				23.5	23.5	N/A	N/A
Average corrected (i.e., corrected for air kerma overestimation) dose (Gy) for these cases	V	4.0				4.0	4.0	N/A	N/A
# of these cases with corrected absorbed dose ≥3 Gy but <10 Gy	D	44				44.0	44	N/A	N/A
% of cases with corrected absorbed dose ≥3 Gy but <10 Gy compared to total # of cases	D	58%				58%	58%	N/A	N/A
# of these cases with corrected absorbed dose ≥10 Gy but <15 Gy	D	2				2.0	2	N/A	N/A
% of cases with corrected absorbed dose ≥10 Gy but <15 Gy compared to total # of cases	D	2.6%				2.6%	2.6%	N/A	N/A
# of these cases with corrected absorbed dose ≥15 Gy	D	2				2.0	2	N/A	N/A
% of cases with corrected absorbed dose ≥15 Gy compared to total # of cases	D	2.6%				2.6%	2.6%	N/A	N/A
Average effective dose (mSv) for these cases	V	47.4				47.4	47.4	N/A	N/A
# of these cases with effective dose ≥10 mSv but ≤100 mSv	V	68				68.0	68	N/A	N/A
% of cases with effective dose ≥10 mSv but ≤100 mSv compared to total cases	V	89%				89%	89%	N/A	N/A
# of these cases with effective dose >100 mSv	D	5				5.0	5	N/A	N/A
% of cases with effective dose >100 mSv compared to total cases	D	6.6%				6.6%	6.6%	N/A	N/A
C. Broken down by Procedure Type - Electrophysiology:									
# of Cardiac Cath cases with documented absorbed dose (i.e., air kerma & assumes no movement of x-ray tube & pt)	V	44				44.0	44	N/A	N/A
Average fluoro time (min) for these cases	V	17.6				17.6	17.6	N/A	N/A
Average corrected (i.e., corrected for air kerma overestimation) dose (Gy) for these cases	V	0.8				0.8	0.8	N/A	N/A
# of these cases with corrected absorbed dose ≥3 Gy but <10 Gy	D	2				2.0	2	N/A	N/A
% of cases with corrected absorbed dose ≥3 Gy but <10 Gy compared to total # of cases	D	5%				5%	5%	N/A	N/A
# of these cases with corrected absorbed dose ≥10 Gy but <15 Gy	D	0				0.0	0	N/A	N/A
% of cases with corrected absorbed dose ≥10 Gy but <15 Gy compared to total # of cases	D	0.0%				0.0%	0.0%	N/A	N/A
# of these cases with corrected absorbed dose ≥15 Gy	D	0				0.0	0	N/A	N/A
% of cases with corrected absorbed dose ≥15 Gy compared to total # of cases	D	0.0%				0.0%	0.0%	N/A	N/A
Average effective dose (mSv) for these cases	V	21.5				21.5	21.5	N/A	N/A
# of these cases with effective dose ≥10 mSv but ≤100 mSv	V	28				28.0	28	N/A	N/A
% of cases with effective dose ≥10 mSv but ≤100 mSv compared to total cases	V	64%				64%	64%	N/A	N/A
# of these cases with effective dose >100 mSv	D	1				1.0	1	N/A	N/A
% of cases with effective dose >100 mSv compared to total cases	D	2.3%				2.3%	2.3%	N/A	N/A

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4. Training (Include all staff if dealing with radiographic-fluoroscopic use.):									
Total # of radiation safety training hours provided	V	0.00				0.00	0.00	*0.00*	*0.00*
5. Radiation Safety Improvements and/or Additional Comments/Problems:									
Changed trending audit to display only quarterly data (i.e., no monthly breakdown) to be consistent with other trending audits.	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*
Added CT Radiation Summary Charts as part of CT Review (item 1).	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*
Added monitoring of effective doses as part of the Cardiac Cath review (item 3) and a related reference (Table 3).	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*
Changed breakdown of Cardiac Cath review (item 3) from by room to by procedure type (Diagnostic, Interventional, Electrophysiology).	N/A	in 1st Qtr				N/A	in 1st Qtr	*N/A*	*N/A*

D = Discrepancy/Problem Indicator V = Volume Indicator

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Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	2009 Qtrly Average	2009 Total

References with links for Section 1 above

Table 1. Relative radiation level designations along with common example examinations for each classification

Relative Radiation Level*	Effective Dose Estimate Range	Example Examinations
None	0	Ultrasound, MRI
Minimal	<0.1 mSv	Chest radiographs, hand radiographs
Low	0.1-1 mSv	Pelvis radiographs, mammography
Medium	1-10 mSv	Abdomen CT, barium enema, nuclear medicine bone scan
High	10-100 mSv	Abdomen CT without and with contrast, whole body PET

*The RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, the region of the body exposed to ionizing radiation, the imaging guidance that is used, etc). The RRLs for these examinations are designated as NS (not specified)

Taken from ACR Appropriateness Criteria® Radiation Dose Assessment Introduction (Relative Radiation Level Information).

Table 2

Adult Effective Doses for Various CT Procedures

Examination	Average Effective Dose (mSv)	Values Reported in Literature (mSv)
Head	2	0.9–4.0
Neck	3	
Chest	7	4.0–18.0
Chest for pulmonary embolism	15	13–40
Abdomen	8	3.5–25
Pelvis	6	3.3–10
Three-phase liver study	15	
Spine	6	1.5–10
Coronary angiography	16	5.0–32
Calcium scoring	3	1.0–12
Virtual colonoscopy	10	4.0–13.2

Taken from Mettler FA, Jr., Huda W, Yoshizumi TT, Mahesh M. Effective doses in radiology and diagnostic nuclear medicine: a catalog. Radiology 2008; 248(1):254-263.

References with links for Sections 2 & 3 above

Table II. Radiation-Induced Skin Injuries

Effect	Typical Threshold Absorbed Dose (Gy)*	Hours of Fluoroscopic "On Time" to Reach Threshold" at: Usual Fluoro Dose Rate of 0.02 Gy/min (2 rad/min)	High-Level Dose Rate of 0.2 Gy/min (20 rad/min)	Time to Onset of Effect**
Early transient erythema	2	1.7	0.17	hours
Temporary epilation	3	2.5	0.25	3 wk
Main erythema	6	5.0	0.50	10 d
Permanent epilation	7	5.8	0.58	3 wk
Dry desquamation	10	8.3	0.83	4 wk
Invasive fibrosis	10	8.3	0.83	
Dermal atrophy	11	9.2	0.92	14 wk
Telangiectasis	12	10.0	1.00	52 wk
Moist desquamation	15	12.5	1.25	4 wk
Late erythema	15	12.5	1.25	6-10 wk
Dermal necrosis	18	15.0	1.50	10 wk
Secondary ulceration	20	16.7	1.67	6 wk

* The unit for absorbed dose is the gray (Gy) in the International System of units. One Gy is equivalent to 100 rad in the traditional system of radiation units.
" Time required to deliver the typical threshold dose at the specified dose rate
"" Time after single irradiation to observation of effect

Taken from FDA's Avoidance of Serious X-ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures.

Table 3

Adult Effective Doses for Various Interventional Radiology Procedures

Examination	Average Effective Dose (mSv)*	Values Reported in Literature (mSv)
Head and/or neck angiography	5	0.8–19.6
Coronary angiography (diagnostic)	7	2.0–15.8
Coronary percutaneous transluminal angioplasty, stent placement, or radiofrequency ablation	15	6.9–57
Thoracic angiography of pulmonary artery or aorta	5	4.1–9.0
Abdominal angiography or aortography	12	4.0–48.0
Transjugular intrahepatic portosystemic shunt placement	70	20–180
Pelvic vein embolization	60	44–78

* Values can vary markedly on the basis of the skill of the operator and the difficulty of the procedure.

Taken from Mettler FA, Jr., Huda W, Yoshizumi TT, Mahesh M. Effective doses in radiology and diagnostic nuclear medicine: a catalog. Radiology 2008; 248(1):254-263.

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ALARA-Radiation Exposure

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		Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	2009 Qtrly Average	2009 Total
1. Personnel Exposure Records/ALARA Investigational Levels (see below):									
A. Radioactive Materials Use:									
a) Follow-up on previous quarter's review (see detailed reports above or summaries below)									
b) # of times ALARA Quarterly Investigational Level I (10% of ¼ annual limit) was exceeded	D	0				0.0	0	0.0	0
c) # of times ALARA Quarterly Investigational Level II (30% of ¼ annual limit) was exceeded	D	0				0.0	0	0	0
B. Radiographic-Fluoroscopic Use:									
a) Follow-up on previous quarter's review (see detailed reports above or summaries below)									
b) # of times ALARA Quarterly Investigational Level I (10% of ¼ annual limit) was exceeded	D	2				2.0	2	0.8	3
By Type: **# of times Whole Body Effective Dose Equivalent ALARA I @ 125 mrem was exceeded**	D	1				1.0	1	0.3	1
Then by Employee: Anesthesiologist/Pain Clinic - Badge # 1048 qtrly total in mrem	D	14				14	14	51	202
Anesthesiologist/Pain Clinic - Badge # 1065 qtrly total in mrem	D	**212**				212	212	37	148
By Type: **# of times Lens Dose Equivalent ALARA I @ 375 mrem was exceeded**	D	1				1.0	1	0.5	2
Then by Employee: RN/Cath Lab - Badge # 534 qtrly total in mrem	D	279				279	279	340	1,360
Anesthesiologist/Pain Clinic - Badge # 1048 qtrly total in mrem	D	48				48	48	174	696
Anesthesiologist/Pain Clinic - Badge # 1065 qtrly total in mrem	D	**708**				708	708	124	497
c) # of times ALARA Quarterly Investigational Level II (30% of ¼ annual limit) was exceeded	D	0				0.0	0	0	0
2. I-125/I-131 Bioassay Results:									
a) Nuclear Medicine									
# of employees having bioassays	V	4				4.0	4	1.3	5
# of times bioassays performed	V	4				4.0	4	1.8	7
# of administrations > 1 mCi of I-131 as NaI in solution	V	0				0.0	0	0.0	0
# of administrations > 10 mCi of I-131 as NaI in capsule	V	4				4.0	4	1.8	7
# of times bioassays not performed within 6-72 hours post administration	D	0				0.0	0	0.0	0
# of times bioassay results were > minimal detectable activity (MDA) of the counting system	D	0				0.0	0	0.0	0
# of times bioassay results required action and/or inclusion in Total Effective Dose Equivalent	D	0				0.0	0	0.0	0
b) Research - Not performing iodinations at this time - no bioassays done	V	N/A				N/A	N/A	N/A	N/A
3. Pregnant Radiation Workers:									
# of declared pregnant radiation workers	V	0				0.0	0	0.0	0
4. Quarterly Area Monitors Involving Radioactive Materials:									
NM2 monitor - wall in main hallway outside Nuclear Medicine (i.e., outer wall of hot lab) qtrly total in mrem	V	2				2.0	2	6.3	25
NM3 monitor - wall in main hallway outside Nuclear Medicine (i.e., outer wall of hot lab) qtrly total in mrem	V	0				0.0	0	0.0	0
RES1 monitor - doorway of research radioactive waste storage room qtrly total in mrem	V	0				0.0	0	0.0	0
# of area monitors with readings > 100 mrem for the current calendar year (i.e., 2010)	D	N/A				N/A	N/A	N/A	0
5. Sanitary Sewer Disposal of Radioactive Material:	V	N/A				N/A	N/A	N/A	N/A
6. Radiation Safety Improvements and/or Additional Comments/Problems:									
Added links in trending/detailed reports to staff exposure trending reports for employees who exceed ALARA during the year.	N/A	in 1st Qtr				N/A	in 1st Qtr	N/A	N/A

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ALARA-Radiation Exposure

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Quarterly ALARA Levels & Annual Limits are expressed in mrem	ALARA Quarterly Investigational Levels: Level I (10% of ¼ annual limits)	Level II (30% of ¼ annual limits)	Annual Limits*
Whole Body (WB) Deep Exposure (DDE = Deep Dose Equivalent) (if lead/lead equivalent apron **not** used)	125	375	5,000
Whole Body Effective Dose Equivalent (WB EDE) = 0.3 x DDE (due to use of lead/lead equivalent apron)	125	375	5,000
Lens of Eye Exposure (LDE = Lens Dose Equivalent)	375	1,125	15,000
WB Shallow (Skin) Exposure (SDE = Shallow Dose Equivalent)	1,250	3,750	50,000
Extremity Shallow Exposure (SDE = Shallow Dose Equivalent)	1,250	3,750	50,000

* Annual Occupational Dose Limits for Adults based on NRC Regulations

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Prostate Brachytherapy

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		Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	2010 Qtrly Average	2010 Total	2009 Qtrly Average	2009 Total
Review of VA Patients being sent out for prostate brachytherapy at a non-VA institution.									
1. "Procedure Record" (i.e., non-VA institution's written directive) **Review:**									
# of VA patients sent out for prostate brachytherapy at a non-VA institution	V	2				2.0	2	1.5	6
# of times # of implanted seeds did not equal # of seeds on the prescription plan	D	0				0.0	0	0.5	2
# of times total dose delivered differed from the prescribed dose by 20% or more (i.e., # seeds used vs. plan)	D	0				0.0	0	0.0	0
# of other deficiencies noted or found	D	0				0.0	0	0.0	0
2. "Special Radiation Physics Consult" (i.e., non-VA institution's review of post implant CT) **Review:**									
# of times implanted seeds could not be located on post implant CT	D	0				0.0	0	0.3	1
3. Post Implant CT Review by non-VA institution's Medical Physicist:									
# of times implanted seeds found outside of the treatment area	D	1				1.0	1	1.3	5
4. Post Implant CT Review by VA Radiologist:									
# of times implanted seeds found outside of the treatment area	D	0				0.0	0	0.5	2
5. Medical Review by VA Urologist:									
# of times major complications found other than minor, but expected routine complications	D	0				0.0	0	0.0	0
		1 Pt Review Pending							
6. Radiation Safety Improvements and/or Additional Comments/Problems:									
Developed trending report & detailed audit for prostate brachytherapy which included data from 2008-2009.	N/A	in 1st Qtr				N/A	in 1st Qtr	N/A	N/A

D = Discrepancy/Problem Indicator V = Volume Indicator

Veterans Health Administration (VHA) Pharmaceutical Management Assessment Final Report

Results from Lexington VAMC, Lexington, KY

November 13, 2009

Submitted to:

Department of Veterans Affairs
Veterans Health Administration
Office of Safety, Health, Environmental and Emergency Management
Office of the Deputy Under Secretary for Operations and Management

Prepared by:

Booz | Allen | Hamilton

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1 Executive Summary

A site assessment was conducted by the VHA Pharmaceutical Management Assessment Team from Monday, August 31, 2009 through Friday, September 4, 2009. The Assessment Team included Tim Killian (Waste Management) and Tom Pape (Occupational Safety and Health). This site visit was conducted as part of a larger effort to develop a cradle-to-grave (or cradle) strategy to enhance the Veterans Health Administration's (VHA's) Pharmaceutical Management Capabilities. The Assessment Team appreciated the cooperation and enthusiasm of the Lexington VAMC staff and their willingness to assist ensuring that the visit was a success.

The Lexington Veterans Affairs Medical Center (VAMC) is a two-division, tertiary care medical center. The Cooper Division, built adjacent to the University of Kentucky, offers primary and specialty outpatient care, inpatient acute medical, neurological, surgical and psychiatric care. The Leestown Division has a Community Living Center with hospice and respite services, primary care, home based primary care, prosthetics, optometry, mental health and substance abuse treatment, women's health, acute rehabilitation, and Post-Traumatic Stress Disorder residential rehabilitation treatment. The veteran population in Lexington's primary service area is estimated at more than 92,000. The Lexington VAMC is primarily affiliated with the University of Kentucky Colleges of Medicine and Dentistry. The medical center also holds affiliations with 31 additional colleges and universities in Kentucky.

With respect to the Lexington VAMC exemplary capabilities, the VHA Pharmaceutical Management Assessment Team observed that the Cooper Division has a fully compliant radiation safety program that includes radiopharmaceuticals. The Nuclear Medicine Department and the Radiation Safety Officer (RSO) are safely and correctly managing all radiopharmaceuticals from delivery to the facility to disposal.

In addition, the Leestown Division is a Conditionally Exempt Small Quantity Generator (CESQG) and is subject to limited federal requirements. The Leestown Division however is complying with many requirements above and beyond what is required of them. They have notified the state and received an EPA Identification Number. Hazardous waste is shipped offsite with appropriate hazardous waste manifests and with the relevant Land Disposal Restriction (LDR) notifications to the treatment, storage, and disposal facility (TSDF).

With respect to the Pharmaceutical Handling and Use capabilities, the Assessment Team recommends that the Lexington VAMC develop a comprehensive list of OSHA hazardous pharmaceuticals and develop a written hazardous drug management plan. The facility needs to develop a standardized pharmaceutical handling policy that addresses all workplace exposures to

3 Methodology

Prior to the site visits, a Regulatory Baseline Assessment was conducted to establish the baseline Federal and state regulations, industry best practices, and VA policies with respect to Pharmaceutical Product Management, Pharmaceutical Handling and Use, and Waste Management practices. Through this baseline review, 40 capabilities were defined, which serve as the basis for this Pharmaceutical Management assessment protocol. The following discussion provides a high level summary of the overall assessment protocol and the associated measurement scheme.

3.1 CAPABILITY DESCRIPTION

The capabilities assessed during the Pharmaceutical Management site visit are consolidated into the following four categories:

- **Program Level** capabilities ensure that facilities incorporate Green Environmental Management Systems (GEMS) planning and guidance as the foundation for implementing pharmaceutical management capabilities. The key program level capability is based upon GEMS requirements.

- **Product Management** capabilities ensure that facilities and personnel manage pharmaceuticals according to regulatory requirements, VHA policies, and related best management practices. These capabilities are crucial to the success of VHA pharmaceutical management programs:

    - Product Ordering / Procurement
    - Inventory Management
    - Performance Management
    - Reverse Distribution

- **Pharmaceutical Handling and Use** capabilities ensure appropriate handling and use of non-hazardous, hazardous, and radioactive pharmaceuticals. These capabilities are crucial to effective pharmaceutical management, as well as environmental, and occupational safety and health management capabilities:

    - Local Policies/Practices
    - Hazard Communication Program
    - Training
    - Medical Surveillance and Recordkeeping
    - Labeling of Pharmaceuticals
    - Hazard/Exposure Controls
    - Controlled Substances/Non-Hazardous Pharmaceuticals Specific Considerations
    - Hazardous Pharmaceuticals Specific Considerations
    - Nuclear Medicine/Radiopharmaceuticals

- Emergency Procedures
- Dispensing/Compounding
- Administering Practices
- Contamination Control/Residue Management
- Disposal Procedures

- **Waste Management** capabilities ensure that facilities manage pharmaceutical waste according to regulatory requirements, VHA policies, and related best management practices. The following waste management capabilities are critical to all VAMCs:

  - Pharmaceutical Management Through Reverse Distribution
  - Hazardous Waste Identification
  - Proper Management of Non-Hazardous Pharmaceutical Waste
  - Conditionally Exempt Small Quantity Generator (CESQG) Requirements.
  - Small Quantity Generator (SQG) Accumulation Requirements
  - SQG Recordkeeping and Reporting Requirements
  - SQG Container Management Standards
  - SQG Emergency Procedure Requirements
  - Large Quantity Generator (LQG) Accumulation Requirements
  - LQG Recordkeeping and Reporting Requirements
  - LQG Container Management Standards
  - LQG Emergency Procedure Requirements
  - LQG Air Emission Requirements
  - Pre-Transport and Manifest requirements
  - Satellite Accumulation Point (Area) Management Standards
  - Preparedness and Prevention Standards
  - Land Disposal Restriction (LDR) Notification Requirements
  - Drug Enforcement Agency (DEA) Regulations for the Management of Controlled Substances
  - Nuclear Regulatory Commission (NRC) Requirements for the Management of Radioactive Waste
  - Radioactive Mixed Waste Conditional Exemption
  - Pharmaceutical Take-Back Initiatives

3.2 CAPABILITY ASSESSMENT AND MEASUREMENT

After the Assessment Team defined the critical capabilities, the following measurement scheme was developed as a tool for describing how the capabilities are demonstrated at the VAMC. This measurement scheme incorporates a four level scale as follows:

- **Exceeds:** This facility goes beyond demonstrating compliance with all applicable Federal/state regulatory and VHA policy requirements related to

4 Overall Program Capabilities

Table 2 below provides a summary of the pharmaceutical management capabilities demonstrated at Lexington VAMC with respect to the four Pharmaceutical Management Capability areas (Program Level, Product Management, Pharmaceutical Handling and Use, and Waste Management). Capabilities not evaluated (e.g., may not apply to facility) are evident by an open circle in the capability element box.

A detailed discussion of the "Exceeds" capabilities or those where enhancement of capabilities is suggested based on capabilities demonstrated during the site visit is provided in Section 5.

Pharmaceutical Management Capability Measurement Legend

●	**Exceeds**	Facility goes beyond demonstrating compliance with applicable Federal/state regulatory and VHA policy requirements by also employing best management practices.
◕	**Meets**	Compliance with applicable Federal/state regulatory and VHA policy requirements demonstrated.
◑	**Partially Meets**	Compliance with most of the applicable Federal/state regulatory and VHA requirements demonstrated.
◔	**Needs Attention**	Significant gaps in applicable Federal/state regulatory and VHA requirements identified.
○	**Not Applicable**	This capability does not apply to this VHA facility.

Table 2. Summary of Lexington VAMC Capabilities

Capability	Exceeds	Meets	Partially Meets	Needs Attention	Not Applicable
1.0 Program Level					
1.1 Green Environmental Management System		◕			
2.0 Product Management					
2.1 Product Ordering / Procurement		◕			
2.2 (a) Inventory Management – Pharmacy		◕			
2.2 (b) Inventory Management – Pharmaceutical Receiving and Storage Areas					○
2.2 (c) Inventory Management – Investigational and Research Pharmacies					○
2.2 (d) Inventory Management – Patient Care Wards		◕			
2.3 Performance Management		◕			
2.4 Reverse Distribution		◕			
3.0 Pharmaceutical Handling and Use					
3.1 Local Policies/Practices			◑		
3.2 Hazard Communication Program		◕			
3.3 Training			◑		
3.4 Medical Surveillance and Recordkeeping		◕			
3.5 Labeling of Pharmaceuticals			◑		
3.6 Hazard/Exposure Controls		◕			
3.7 Controlled Substances/Non-Hazardous Pharmaceuticals Specific Considerations			◑		
3.8 Hazardous Pharmaceuticals Specific		◕			

Capability	Exceeds	Meets	Partially Meets	Needs Attention	Not Applicable
Considerations					
3.9 Nuclear Medicine/Radiopharmaceuticals Specific Considerations	●				
3.10 Emergency Procedures		◕			
3.11 Dispensing/Compounding		◕			
3.12 Administering Practices			◑		
3.13 Contamination Control/Residue Management		◕			
3.14 (a) Disposal Procedures – Pharmacy		◕			
3.14 (b) Disposal Procedures – Oncology Ward			◑		
3.14 (c) Disposal Procedures – Patient Care Wards			◑		
3.14 (d) Disposal Procedures – Research			◑		
4.0 Waste Management					
4.1 Pharmaceutical Management through Reverse Distribution			◑		
4.2 (a) Hazardous Waste Identification – Pharmacy		◕			
4.2 (b) Hazardous Waste Identification – Oncology			◑		
4.2 (c) Hazardous Waste Identification – Patient Care Wards				◔	
4.2 (d) Hazardous Waste Identification – Research				◔	
4.3 Proper Management of Non-Hazardous Pharmaceutical Waste		◕			
4.4 CESQG Requirements	●				
4.5 SQG Accumulation Requirements		◕			
4.6 SQG Recordkeeping and Reporting Requirements		◕			
4.7 SQG Container Management Standards		◕			
4.8 SQG Emergency Procedure Requirements		◕			
4.9 LQG Accumulation Requirements					○
4.10 LQG Recordkeeping and Reporting Requirements					○
4.11 LQG Container Management Standards					○
4.12 LQG Emergency Procedure Requirements					○
4.13 LQG Air Emission Requirements					○
4.14 Pre-Transport and Manifest Requirements		◕			
4.15 (a) Satellite Accumulation Point (Area) Management Standards – Pharmacy			◑		
4.15 (b) Satellite Accumulation Point (Area) Management Standards – Oncology			◑		
4.15 (c) Satellite Accumulation Point (Area) Management Standards – Patient Care Wards				◔	
4.15 (d) Satellite Accumulation Point (Area) Management Standards – Research				◔	
4.16 Preparedness and Prevention Standards		◕			
4.17 LDR Notification Requirements	●				
4.18 DEA Regulations for the Management of Controlled Substances		◕			
4.19 NRC Requirements for the Management of Radioactive Waste		◕			
4.20 Radioactive Mixed Waste Conditional Exemption					○
4.21 Pharmaceutical Take-Back Initiatives					○

- Chemotherapy bags are pre-printed with a cytotoxic warning label
- Facility has a Chemotherapy Drug Spill Clean-Up Procedure
- The Chemical Hygiene Plan in Research includes pharmaceuticals
- Yellow trace chemotherapy containers are provided to the Hospice Ward (Leestown Division) when they receive a patient who has been administered chemotherapy within the last 72 hours
- The VAMC has developed and implemented an on-line waste reporting system. Waste that is placed in a satellite accumulation area at the VAMC is reported to the GEMS Coordinator online, identifying materials that need to be collected and disposed

5.1.2 Pharmaceutical Handling and Use Exemplary Practices

5.1.2.1 Nuclear Medicine/Radiopharmaceuticals Specific Considerations

The Lexington VAMC has an exemplary radiation safety program in place that includes radiopharmaceuticals. The program demonstrated all the characteristics of a fully compliant nuclear medicine/radiopharmaceutical activity including:

- RSO has adequate resources and time to administer radiopharmaceutical program
- Appropriate signage in use
- Radioactive materials were properly labeled
- Safety instruction provided initially and annually to employees
- Radiation monitoring was observed and contamination control practices are in place
- Training provided for all employees that may come into contact with radiopharmaceuticals or residues
- Radiation Safety Committee meets regularly and monitoring data is presented
- ALARA (As Low As Reasonable Achievable) principles are employed with regard to limiting exposures
- Employees are informed of exposures and are a part of radiation safety program

5.1.3 Pharmaceutical Waste Management Exemplary Practices

5.1.3.1 Conditionally Exempt Small Quantity Generator (CESQG) Requirements

A Conditionally Exempt Small Quantity Generator (CESQG) generates less than 100 kg of hazardous waste per calendar month *and* no more than 1 kg of acutely hazardous waste per calendar. Hazardous waste generated by a CESQG is not subject to specific management standards for accumulation under the federal hazardous waste regulations provided the CESQG does not accumulate more

addresses all aspects of controlling exposures to all pharmaceuticals that may pose a health risk.

The facility should develop a list of OSHA hazardous pharmaceuticals and develop a hazardous drug plan in accordance with VHA Information Letter 10-2004-019 and the Industrial Hygiene Guidebook, Chapter 11.1. The plan should include at a minimum: roles and responsibilities; identification of hazards; recommended work practices and personal protection; labeling; training; contamination control and spill cleanup; emergency procedures; medical surveillance; and disposal procedures. The plan should integrate and harmonize with other policies and programs (e.g., bloodborne pathogens, hazard communication, and waste management) to the greatest extent possible.

5.2.1.2 Training

The Training capability is based on the facility having formal, documented training programs in place for the handling, use and proper disposal of pharmaceuticals encountered in the workplace. Personnel receiving training should include all personnel that may come in contact with pharmaceuticals, pharmaceutical residues, or pharmaceutical waste in the course of their normal duties. This would include receiving, pharmacy, environmental management services, medical, and volunteer staff.

At the Lexington VAMC, there is no formal training that covers all types of pharmaceutical handling and use scenarios, or that addresses all types of pharmaceuticals found at the Lexington VAMC (e.g., non-hazardous drugs, controlled substances, hazardous drugs, radiopharmaceuticals). Some formal training is provided with regard to chemotherapy drugs. Formal training is provided for pharmacists and pharmacy technicians handling a chemotherapy preparation that is part of maintaining their chemotherapy credentials. Same is true for the Oncology nursing staff who receive training on the handling and use of chemotherapy drugs. Nuclear medicine staff receive radiation safety training that includes handling of radiopharmaceuticals.

Other formal training is provided that relates to pharmaceuticals, but is not specifically intended to address worker exposures to pharmaceuticals. Non-oncology healthcare workers formal training is limited to "standard" precautions for administering drugs to patients designed to protect against bloodborne pathogens and for infection control. The nursing staff does not receive formal training on handling of pharmaceuticals or hazardous pharmaceuticals but does receive in-service briefings/alerts on new pharmaceuticals.

The facility needs to develop training for healthcare workers with regard to pharmaceuticals in the workplace including hazard recognition, proper handling, PPE use and disposal procedures.

Joint Commission Resources Consulting - Life Safety Consultant Visit on October 1-2, 2009 at VA Medical Center, Lexington, KY

An Action Plan with a total of 67 issues was developed by Sally Higgins, local Safety Manager based on the above visit that included 1 issue pertaining to the Radiation Safety Program:

	ISSUE	LOCATION	CONCERN	ACTION	EP	UPDATE DUE	TARGET DATE	COMPLETION DATE	RESPONSIBLE PERSON
18	Lead apron tracking	Radiologic/ Fluoroscopic Use Areas	Additional tracking item (i.e., fabric condition) for lead apron	Add to inspection log: Fabric condition Yes/No				11/6/2009: Updated apron log with November inspection.	M. Hackett Updated apron log with November inspection.

The local Safety Manager also noted 3 "Best Practices" based on the above visit which included the Radiation Safety Program:

2. Hot Lab - control of hot material from use to disposal; apron log was one of the tighter systems observed

DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: APR 19

From: Deputy Under Secretary for Health for Operations and Management

Subj: Security for Radioactive Materials at Veterans Health Administration (VHA) Facilities

To: Network Director (10N1-23)

1. The VHA National Health Physics Program (NHPP) issues permits to use radioactive materials to VHA facilities. Those facilities must comply with applicable regulations and orders established by the Nuclear Regulatory Commission (NRC) for safe uses and for security of radioactive materials.

2. The purpose of this memorandum is to reemphasize the importance of security for radioactive materials at VHA facilities. The regulatory requirements for security are in Title 10 Code of Federal Regulations (CFR) 20.1801 and 20.1802. These regulations require VHA facilities with a permit for radioactive materials uses to secure the materials from unauthorized removal or access and to maintain constant visual surveillance for materials not in storage. In addition to requirements in 10 CFR 20, some facilities with larger activity sealed sources must comply with specific NRC orders.

3. The National Radiation Safety Committee (NRSC) has an agenda item to review the status of security at each quarterly meeting. The NRSC requires NHPP to complete the following routine actions related to security:

a. Focusing to security during routine, core inspections at VHA facilities including a review of receipt of radioactive materials, especially outside of normal business hours.

b. Maintaining a centralized Web based inventory to track VHA sealed sources.

c. Requiring two delay methods for sealed sources in storage and not being used at the current time, including those being used on a routine basis.

d. Requiring facilities to dispose or transfer disused sealed sources (i.e., sources not used for their clinical or research purpose for more than 24 months).

e. Making available security-related information on the NHPP Intranet Web site in newsletters, frequently asked questions, and other information resources.

f. Providing detailed requirements to facilities subject to the NRC order for increased controls.

4. The NHPP expectations for security at the facility level include, but are not limited to the following:

a. Ensuring appropriate level of coordination with VA Police Service on security for radioactive materials, especially for delivery of radioactive materials.

b. Reviewing, as part of the annual review under 10 CFR 20, security-related issues such as permittee footprint (i.e., approved locations of use, delivery, or storage) and the status of sealed sources.

c. Developing, implementing, and maintaining security for radioactive materials, as needed, to ensure compliance with NRC regulations to include implementation of two delay methods for sealed sources and compliance with applicable NRC orders.

d. Implementing, for research uses, VHA Handbook 1200.6, "Control of Hazardous Agents In VA Research Laboratories."

e. Maintaining sealed source inventories on NHPP Intranet Web site and dispose or transfer disused sources, as needed.

5. If you have questions about required actions or security in general, please contact Gary E. Williams, NHPP, at (501) 257-1572 gary.williams3@va.gov.

William Schoenhard

William Schoenhard, FACHE

cc: Chair, National Radiation Safety Committee
Director, NHPP

Security for Radioactive Materials

Facility & Station No.: Lexington VAMC (596)

Description of Radioactive Materials	Quantity	Security Provision for Materials Used & Stored
Patient doses for studies in Nuclear Medicine (e.g., Ga-67, I-131, Tc-99m labeled radiopharmaceuticals, etc.) with diagnostic activities levels from 0.5 to 45 mCi per dose and therapeutic activities levels from 10 to 250 mCi per dose depending on the patient and type of study. The majority (>90%) of the doses are unit doses that are provided by a local radiopharmacy.	Total activity unlikely to exceed 500 mCi in house at any one time. 10-30 unit doses per day depending on the patient schedule and availability of Tc-99m (i.e., recent world-wide shortage of Mo-99/Tc-99m generator).	After hour deliveries come in via the AOD & VA Police. Police deliver or escort courier to Nuclear Medicine (NM) - locked delivery room just outside the hot lab. Deliveries during normal working hours from the local radiopharmacy come directly to NM & technologists escort the courier into the locked hot lab while shipments from the manufacturer go through the warehouse & are promptly picked up by the Radiation Safety Officer (RSO) or the technologists but may be delivered to NM. Doses are stored in the hot lab which is locked at all times until their use. It has a combination lock and a dead bolt which is locked after hours. Only the RSO and the technologists know the combination (changed after a technologist leaves) and are issued hot lab keys (i.e., different key for the other NM locks). When these doses are in use, they must be under constant surveillance by a NM technologist unless they are in a secured restricted room. Annual radiation safety training for AOD, Nuclear Medicine, VA Police, and the warehouse staff includes security of radioactive materials.

Sealed sources in Nuclear Medicine.	A. ~89 mCi Cs-137 * B. ~ 3 mCi Co-57 * C. Multiple <1 mCi with most being exempt sources * A. & B. are maintained on NHPP centralized web based inventory (i.e., >1 mCi).	All sealed sources except for two exempt sources are stored in the locked hot lab. Cs-137 calibration source is stored in a locked closet in the hot lab. Other sources that are not used daily are stored in a locked cabinet within the hot lab unless they are exempt sources. All sealed sources are inventoried quarterly & the Cs-137 calibration source has additional monthly checks. When these sources are in use, they must be under constant surveillance by a NM technologist or the RSO unless they are in a secured restricted room. As noted above, the locked delivery room outside of the hot lab and the locked NM area provide extra security for the hot lab after hours.
Radioactive material (unsealed material, e.g., H-3, P-32, etc.) used for research studies with activities levels from 0.1 to 5.0 mCi per vial.	A. <5 mCi H-3 B. <3 mCi I-125 Very limited use in research with 1-5 shipments per quarter and varies slightly from month to month.	All orders for radioactive material must be pre-approved by the RSO before the order is placed. All shipments are delivered to the warehouse and then to the RSO who monitors and inventories the radioactive material. The radioactive material is used and stored in approved research labs that are within research security doors. Annual radiation safety training for research staff includes security of radioactive materials.

Sealed sources in Research.	A. ~9 mCi Ni-63 * B. ~10 mCi Ni-63 * C. Multiple <1 mCi with most being exempt sources * A. & B. are maintained on NHPP centralized web based inventory (i.e., >1 mCi).	Sealed sources used as internal calibration or check sources for radiation detection equipment are in core labs that are within the research area security doors. All other sources are stored in a locked cabinet within the NM's hot lab. This includes the two NHPP inventoried Ni-63 ECD sources that will be disposed of since they are no longer being used. All sealed sources are inventoried quarterly.

Prescriptive Requirements for Radiation Safety Committees

1. Attached documents with details and requirements:

   - DUSHOM memorandum dated April 12, 2010
   - NHPP FAQ 08-04 (revised April 21, 2010)
   - Example Radiation Safety Committee minutes (tabular)
   - Example Radiation Safety Committee minutes (narrative)
   - Radiation Safety Committee audit worksheet

2. Effective date for compliance for committee meetings held on or after July 15, 2010.

3. Point of contact for comments or questions: Gary E. Williams, NHPP, at 501-257-1572 or gary.williams3@va.gov.

DUSHOM memorandum dated April 12, 2010

Note:

The attachment to the 10N memorandum is not included since a revision to the example format was prepared based on comments received from various reviewers.

DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: APR 12 2010

From: Deputy Under Secretary for Health for Operations and Management

Subj: Radiation Safety Committees at Veterans Health Administration (VHA) Facilities

To: Network Directors (10N1-23)
Medical Center Director (00)

1. The VHA National Health Physics Program (NHPP) issues permits to use radioactive materials to VHA facilities. The facilities must comply with applicable regulations, permit conditions, and required actions in VHA Directive 1105.01, "Management of Radioactive Materials." Paragraph 4e has requirements for the facility Radiation Safety Committee.

2. This memorandum announces prescriptive requirements for the committee which are being established by NHPP under the National Radiation Safety Committee. NHPP will inspect for compliance to these requirements for committee meetings that are held on or after July 15, 2010.

3. The prescriptive requirements include, but are not limited to, the following:

a. Review and administrative oversight of Radiation Safety Committee minutes by a higher-level committee within the facility.

b. Prepare and submit Radiation Safety Committee minutes to the higher-level committee within 30 days after the Radiation Safety Committee meeting.

c. Review and signature by the director for Radiation Safety Committee minutes not more than 45 days after the meeting.

d. Use of an agenda with old business, new business, and standing agenda items listed to include standing agenda items for dosimetry results for workers, status of all procedures requiring a written directive, status of footprint management, and status for security.

e. Use of an attendance matrix listing committee members and whether a member attended an individual meeting.

f. Use of a tracking matrix with unresolved items assigned a tracking number when first identified at a Radiation Safety Committee meeting and items tracked to closure.

Radiation Safety Committees at Veterans Health Administration (VHA) Facilities

g. Use of standardized formats for Radiation Safety Committee minutes to include a file with supporting documents used during committee meetings stored in hard copy or electronic format for ease of review by external inspectors.

4. NHPP will issue a revision to the Frequently Asked Question (FAQ) 08-04 with more details about requirements for Radiation Safety Committees. This revised FAQ will be posted on the NHPP Intranet Web site and distributed to Radiation Safety Officers.

5. If you have any questions about required actions, please contact Gary E. Williams, NHPP, at (501) 257-1572 gary.williams3@va.gov.

William Schoenhard

William Schoenhard, FACHE

cc: Chair, National Radiation Safety Committee
Director, NHPP

Attachment

NHPP FAQ 08-04 (revised April 21, 2010)

NHPP Frequently Asked Question 08-04
April 21, 2010 [revised]

Question

What are the requirements for Radiation Safety Committee meetings, oversight, and the minutes prepared to document the committee meetings.

Answer

The National Radiation Safety Committee is establishing the following prescriptive requirements related to Radiation Safety Committee meetings.

The prescriptive requirements focus to the content of the minutes and supporting documents. This FAQ also has example formats that might be adapted for use by individual facilities.

NHPP inspections will evaluate compliance with these prescriptive requirements for committee meetings that are held on or after July 15, 2010.

Overview

Each permittee must have a functional Radiation Safety Committee as required by VHA Directive 1105.01, "Management of Radioactive Materials." This directive was revised and reissued on October 7, 2009. Paragraph 4e has detailed guidelines for the committee. The guidelines are also applicable to the Radiation Safety Officer.

In addition to the requirements in VHA Directive 1105.01, a broad-scope permittee must have a Radiation Safety Committee consistent with permit commitments and conditions. NUREG-1556, Volume 11, Section 8.7, outlines regulatory guidelines for executive management, the Radiation Safety Committee, and the Radiation Safety Officer. 10 CFR 33.13 has specific requirements for a broad-scope permittee.

See FAQ 02-17 for more details about Radiation Safety Committee guidelines.

The Radiation Safety Committee's general task is to function in conjunction with the Radiation Safety Officer to support the facility director to provide for health and safety and achieve regulatory compliance. Various organizational arrangements are feasible to provide for committee oversight.

Most facilities use a higher-level committee within the facility to provide general administrative oversight and accountability for the Radiation Safety Committee.

The higher-level committees used at various facilities include the Quality Council, the Environment of Care Committee, the Safety and Risk Management Committee, and/or the Hospital Safety Committee depending on the organizational structures within the facility.

Of course, the organizational arrangement or oversight method must not preclude or restrict the ability of the Radiation Safety Committee and Radiation Safety Officer to interact directly with the facility director. Also, the Radiation Safety Committee and Radiation Safety Officer must have stop-work authority.

The oversight committee might provide comments or concurrence for the Radiation Safety Committee actions but must not interfere or restrict any required tasks or functions in VHA Directive 1105.01 or 10 CFR 35.24 for a limited-scope permittee.

For broad-scope permittees, an oversight committee must not interfere or restrict the tasks in VHA Directive 1105.01, 10 CFR 33.13, 10 CFR 35.24, or the guidelines in NUREG-1556, Volume 11, Section 8.7.

Specific Radiation Safety Committee requirements for minutes and oversight

The facility must establish an oversight arrangement with a higher-level committee within the facility assigned to receive and review the Radiation Safety Committee minutes.

The Radiation Safety Committee meetings must be held at least every 6 months and have a meeting quorum of at least one-half of committee members to include both the Radiation Safety Officer and management representative.

Broad-scope permittees should hold meetings at least quarterly.

The Radiation Safety Committee minutes must be prepared and submitted to this oversight committee within 30 days after the committee meeting. The committee minutes must be received and signed by the facility director within 45 days after the Radiation Safety Committee meeting.

The content for the minutes must include the following:

- Agenda or meeting outline with old business, new business, and standing agenda items listed.

  Note: The standing or routine agenda items must include summary dosimetry results for workers, the status of all procedures requiring a written directive, the status of footprint management, and the status for security. If applicable, new business must include reports of spills, incidents, self-identified radiation safety program deficiencies, and results for external audits or inspections.

- Attendance matrix or other listing of the committee members and whether a member attended an individual meeting.

- Tracking matrix or other listing for any unresolved items.

  Note: The unresolved items must be assigned a tracking number when first identified at a committee meeting and these items tracked to closure.

- Summary for committee discussions and deliberations in a narrative or table format with listing or description of committee votes.

The committee deliberations must include, as needed, the review and approval of authorized users, authorized locations of use, evaluation of results for audits or inspections, approval for medical or research protocols, and completion of training for radiation workers and ancillary staff.

The committee minutes including additional or supporting documents used during committee meetings must be stored in a specific location in hard copy or electronic format for ease of review by external inspectors.

The minutes must be maintained for the duration of the permit.

Example Radiation Safety Committee minutes with acceptable formats

The content for facility-level Radiation Safety Committee minutes must conform to the requirements above. Three possible document formats are described below.

The example document formats are for illustration only and should be adjusted, as needed, by individual facilities to include the prescriptive requirements.

Format based on National Radiation Safety Committee

The National Radiation Safety Committee minutes provide an example format for facility-level minutes to include a narrative summary, agenda, attendance matrix, tracking matrix, and results for core performance indicators. These examples do not include all prescriptive requirements for facility-level minutes.

See examples at http://nhpp.med.va.gov/NRSCMinutes.asp.

Format for limited-scope and some broad-scope facilities

An experienced Radiation Safety Officer prepared the template below for minutes that are consistent with the prescriptive requirements above. These minutes are a summary of the committee meeting results in tabular format with the prescriptive requirements included in the format.

Please note the listing of documents available in Radiation Safety Committee files to support the minutes.

Example RSC
Minutes Tabular Apr 1

Format with more detailed information for some broad-scope facilities

A broad-scope facility might use a narrative format. These example minutes are a more detailed narrative than the tabular format. The prescriptive requirements are included in the format.

Example RSC
Minutes Narrative Ap

Facilities or Radiation Safety Officers with specific questions about requirements for Radiation Safety Committee minutes should contact NHPP for assistance.

Example Radiation Safety Committee minutes (tabular)

Veterans Affairs Medical Center
RADIATION SAFETY COMMITTEE

MEETING DATE: 5/11/2010	TIME STARTED: 2:30PM	TIME ENDED: 3:30 PM

Attendance Record:

Membership	Meeting Date:			
	02/23/10	05/11/10	08/24/10	11/16/10
John Sabiston, MD, Chair, Management Representative	P	P		
R.E. Jones, MD, Chief, Nuclear Medicine	P	P		
Sally Ewell, Radiation Safety Officer	P	P		
Rebecca Garris, Industrial Hygiene	P	P		
Susan Harris, RN, Nursing Representative	P	P		
David Hope, MD, Ph.D., Chief, Pathology and Laboratory Medicine	P	P		
Roger Mason, Ph.D., Research Service	O	P		
James Ogleman, MD, Ph.D., Chief, Radiation Oncology	P	P		
Bradley Oxford, AO for Research	P	P		
Robert Shelley, MD, Chief, Radiology	A	P		
Henry Sopwell, Ph.D., Chief Medical Physicist	P	P		
James Tolliver, Radiation Safety Coordinator	P	P		

P= Present O = Absent E = Excused A = Alternate

TOPIC	DISCUSSION – STATUS –EFFECTIVENESS OF PAST ACTIONS	RECOMMENDATION – ACTION Tracking #	RESPONSIBLE PERSONS Date Due
Review of Minutes			
Review of the February 23, 2010 Minutes	The minutes of the February 23, 2010 meeting of the Radiation Safety Committee were distributed electronically previously. There were no corrections or additions to the minutes. These minutes were approved unanimously by all 12 Committee members present.	Closed Unanimous approval	
Old Business			
Increased Controls / Irradiator	Ms. Ewell reported no change in the anticipated date for removal of the irradiator. She reported the status of the irradiator to the NHPP on April 10, and does not expect an assessment by the Global Threat Reduction Initiative (GTRI) this fiscal year.	Closed Unanimous approval #09-02A	
NRC Inspection of April 20 - 22	The NRC inspection of April 20-22, 2009, part of a review of all VA programs offering permanent prostate brachytherapy, remains open.	Open, monitor status of inspection Unanimous approval #09-05A	Ms. Ewell 8/16/10

TOPIC	DISCUSSION – STATUS –EFFECTIVENESS OF PAST ACTIONS	RECOMMENDATION – ACTION Tracking #	RESPONSIBLE PERSONS Date Due
Standing Agenda Items			
Review of Personnel Dosimetry and the ALARA Program	The committee reviewed the Quarterly Review of personnel exposures for the period of January through March, 2010. All radiation exposures were below investigation levels, and collective dose trends were normal.	Continue to monitor Unanimous approval	Ms. Ewell 8/16/10
Radioisotope Research Lab Audit Review	The committee reviewed the Radioisotope Research Lab Audit Review for the period of January through March, 2010. Eighteen radioisotope research laboratories under ten authorized users were audited. No deficiencies or recommendations for improvements were noted.	Continue to monitor Unanimous approval	Ms. Ewell 8/16/10
Review of Incident	No radiological incidents were reported since the last meeting.	Continue to monitor Unanimous approval	Ms. Ewell 8/16/10
Nuclear Medicine QC Review	The committee reviewed the Nuclear Medicine QC Review for the period of January through March, 2010. No deficiencies or recommendations for improvements were noted.	Continue to monitor Unanimous approval	Ms. Ewell 8/16/10

TOPIC	DISCUSSION – STATUS –EFFECTIVENESS OF PAST ACTIONS	RECOMMENDATION – ACTION Tracking #	RESPONSIBLE PERSONS Date Due
Written Directives Procedures Review	The committee reviewed all written directives procedures for the period of January through March, 2010, to ensure that: 1. Written directives were prepared prior to administration. 2. Patient identifications were verified by more than one method. 3. The administration was in accordance with the written directive. 4. Any unintended deviation was identified and evaluated, and appropriate action taken. There were no medical events. All required information was documented, and the Written Directive Procedures Program was evaluated and found to be effective.	Continue to monitor Unanimous approval	Ms. Ewell 8/16/10
Footprint Management Status Review	Closeout surveys were performed in three rooms in Building 6. No new areas of use are proposed.	Continue to monitor Unanimous approval	Ms. Ewell 8/16/10
Security Status Review	Security status and requirements were reviewed for all radioactive material use and storage areas. No deficiencies or recommendations for improvements were noted.	Continue to monitor Unanimous approval	Ms. Ewell 8/16/10

TOPIC	DISCUSSION – STATUS –EFFECTIVENESS OF PAST ACTIONS	RECOMMENDATION – ACTION Tracking #	RESPONSIBLE PERSONS Date Due
New Business			
Close-out Surveys in Building 6	Ms. Ewell presented a summary of survey results for close-out surveys in rooms 1110, 1116, and 1119 in Building 6. Tritium and Carbon-14 were the isotopes of interest. 100% of the surfaces of floors, benches, and walls to a height of six feet were scanned with gas proportional detectors. Static measurements for fixed contamination and wipes for removable contamination were made on a one meter grid on the same surfaces. Finally dose rates were measured in each room. Ms. Ewell discussed the survey results, which were all below accepted release criteria. She recommended that the rooms be released for unrestricted use.	Approve Rooms 1110, 1116, and 1119 for unrestricted use Closed Unanimous approval *Note: Broad-scope permittees have this approval authority if the rooms remain under VHA control but not limited-scope permittees.*	
VHA Directive 1105.01 "Management of Radioactive Materials"	The directive was reissued October 7, and will require minor revisions to the Radiation Safety Program.	Revise manual Unanimous approval #10-05A	Ms. Ewell 8/16/10
Stereotactic Radiosurgery	Dr. Ogleman discussed the peer review process for the Stereotactic Radiosurgery program, and asked that the Committee review the process at the next meeting.	Distribute a report of the reviews at next meeting Unanimous approval #10-05B	Dr. Ogleman 8/16/10

List of Supporting Documents (copies maintained electronically in meeting folder on network drive):

- Quarterly Summary of Personnel Dosimetry Results for January-March 2010
- Radioisotope Research Lab Audit Report for January-March 2010
- Nuclear Medicine QC Review Report for January-March 2010
- Written Directives Review Report for January-March 2010
- Footprint Management Status Review
    - (includes updated list of areas of current and former use and closeout survey documentation for Rooms 1110, 1116, 1119 in Building 6)
- VHA Directive 1105.01
- Handout on stereotactic radiosurgery (points provided by Dr. Ogleman)

Next Meeting: 8/24/10, 2:30-3:30pm, Room A1010A

Review and Approval for Radiation Safety Committee Minutes

Meeting date: May 11, 2010

Submitted:

_____

Sally R. Ewell Date
Radiation Safety Officer

( ) Approved ( ) Disapproved

_____

John D. Sabiston, M.D. Date
Chair, Radiation Safety Committee

( ) Approved ( ) Disapproved

_____

Ralph R. Gentry Date
Director

Notes:
Minutes sent to Environment of Care Committee (*insert date submitted and initials of Radiation Safety Officer*).
Minutes and supporting documents are posted in meeting folder on network drive for access by committee members.

Example Radiation Safety Committee minutes (narrative)

RADIATION SAFETY COMMITTEE MEETING MINUTES
FOURTH QUARTER AND ANNUAL REVIEW Q4-CY2009

LOCATION: **ROOM J232**
DATE: **MARCH 10, 2010**
TIME: **11:00 AM – 12:15 PM**

MEMBERS PRESENT:

1. Radiation Safety Officer (50R)
   Janet Frame, M.S.

2. Chairman, Radiation Safety Committee (115)
   Ira M. Essex, M.D.

3. Management Representative (11D)
   Doyle Winston

4. Research Service Representative (11R)
   Tim Neutron, Ph.D.

5. Radiation Oncology Service Representative (114B)
   Thomas Gibbs, Ph.D.

6. Nuclear Medicine Service Representative (115)
   Roberta Kim, CNMT

7. Radiation Oncology Service Representative (114B)
   Debbie Therapy, R.T.

8. Quality Management (Guest) (11Q)
   Pam Davis, R.N.

MEMBERS ABSENT:

1. Chief, Radiation Oncology Service (114B)
   John Ramsey, M.D.

2. Chief, Radiology Service (114)
   Fred Image, M.D.

3. Medical Service Representative (111G)
   Mary Richmond, M.D.

4. Patient Care Representative (30)
   Vera Britain, R.N.

5. Cardiology Service Representative (111B)
   Brenda Test, M.D.

6. Radiology Service Representative (114)
   Tomas Quick

7. Cardiology Service Representative (111B)
   Harvey Scott, RT

RADIATION SAFETY COMMITTEE MEETING MINUTES
FOURTH QUARTER AND ANNUAL REVIEW CY2009

1) Review of third quarter and special session meeting minutes

Corrections: ___ yes __X__ no Q3-2009 (November 30, 2009)
Corrections: ___ yes __X__ no Special Session (January 13, 2010)

The Committee approved the third quarter and special session meeting minutes as written with no corrections.

ACTION BY COMMITTEE:

APPROVED BY UNANIMOUS VOTE THE THIRD QUARTER AND SPECIAL SESSION MEETING MINUTES AS WRITTEN WITH NO CORRECTIONS

2) Status of new research laboratory authorizations and amendments

The Radiation Safety Officer (RSO) received and reviewed the petitions below and recommended approval for the changes to authorized uses in research:

Change Requests through 1/15/2010

Dr. Applewhite requested the addition of C-14 to his list of authorized radioisotopes. C-14 (in solid form, reference standard on microscope slide) will be used as a calibration standard/reference for studies involving autoradiography. The committee reviewed the health physics report prepared by the RSO. The committee approved the request for the use of C-14 with the conditions as written in the health physics report and with the following limits:

Order Limit:	0.2 mCi	Possession Limit:	0.2 mCi
Max. per Experiment:	0.2 mCi	Yearly Limit:	0.2 mCi

Dr. Maslow requested deletion of Eddie George from his list of authorized personnel to use radioactive materials.

ACTION BY COMMITTEE:

APPROVED BY UNANIMOUS VOTE DR. APPLEWHITE'S REQUEST TO ADD C-14 TO HIS LIST OF AUTHORIZED RADIOISOTOPES

APPROVED BY UNANIMOUS VOTE DR. MASLOW'S REQUEST TO CHANGE THE LIST OF AUTHORIZED PERSONNEL TO USE RADIOACTIVE MATERAIALS

3) Research Service

Losses/Incidents/Spills: The RSO did not receive any reports of, or identify during periodic walkthroughs, any spills or losses of radioactive materials during the fourth quarter.

Monthly Audits Including Security Reviews: Results of monthly (October, November and December) audits were negative for security deficiencies, contamination, or erroneous exposure, with one exception. Dr. Maslow's laboratory in Room 108, Building 22, had a minor amount of removable contamination present on the floor in one location. Decontamination efforts were successful. The RSO met with all laboratory staff and Dr. Maslow to discuss the matter. No other recommendations were deemed necessary by the RSO.

Annual inspection results: Annual audits of radiation safety records and areas of use were performed by the RSO. **Four active** authorized users were audited. **Three** of the four authorized users were found to be in full compliance, no violations, and no recommendations. **One** authorized user had one Level C violation and no recommendations. The violation was not documenting constancy checks of the survey meter on days radioactive material was used.

Two currently inactive authorized users were audited. Both authorized users were found to be in full compliance, no violations, and no recommendations.

The committee reviewed the inspection reports and Dr. Morrow's written corrective action regarding the Level C violation. The committee approved the inspection reports and Dr. Morrow's written corrective action as written.

Closeouts: No closeouts of areas in Research Service were performed during the calendar quarter.

ACTION BY COMMITTEE:

APPROVED BY UNANIMOUS VOTE THE INSPECTION REPORTS AND DR. MORROW'S WRITTEN CORRECTIVE ACTION AS WRITTEN BY UNANIMOUS VOTE

4) Radioactive Drug Research Committee (RDRC)

The RDRC held their fourth quarterly meeting on 1/05/10. No new projects were approved. Meeting minutes were provided for committee review. The committee reviewed and approved of the minutes as written.

ACTION BY COMMITTEE:

APPROVED BY UNANIMOUS VOTE THE RDRC MINUTES

5) Nuclear Medicine Service

Anywhere VHA Medical Center

Audits Including Security Reviews: The RSO completed audits for Nuclear Medicine Service which included the status for compliance for security under 10 CFR 20. The overall results were satisfactory except for on December 31, 2009, when the staff left the facility without knowing the final results of the required weekly smear values. The issue was immediately resolved by the service chief and the RSO with all technologist staff.

The procedure for conducting radiation safety surveys was modified to reflect the expectation that the staff does not leave without knowing the results of all smear values. The committee reviewed and approved of the revised survey procedure and the corrective actions taken by the RSO and the service chief.

Medical Events Including Review of Written Directives: The RSO did not receive any reports of, or identify during periodic walkthroughs or audits, any reports of circumstances that might be a medical event. A review of written directives did not identify any deficiencies or possible medical events.

Incidents/Spills: The RSO did not receive any reports of, or identify during periodic walkthroughs or audits, any reports of circumstances involving incidents/spills during the fourth quarter.

Requests for Changes in Authorized Users: Dr. Essex requested addition of Dr. Sandra Moore as an authorized user for 35.100, 35.200 and 35.300 uses. A written attestation using appropriate NRC forms, a copy of Dr. Moore's board certificate, Dr. Moore's experience and written confirmation of the individual who signed the attestation statements qualifications were provided for committee review. The RSO confirmed that these were the appropriate documents required per regulation and requested that Dr. Moore be approved as an authorized user for 35.100, 35.200 and 35.300 use. The committee approved Dr. Moore for 35.100, 35.200 and 35.300 uses.

Other Nuclear Medicine Clinic

Audits Including Security Reviews: The RSO completed audits for Nuclear Medicine Section which included the status for compliance for security under 10 CFR 20. The results were satisfactory for the fourth quarter without any deficiencies or items of non-compliance being noted.

Locations of Use: A new gamma camera system was installed in November of 2009 and tested for performance and compliance with AAPM guidelines in early January 2010. The camera system was found to be in full

compliance prior to use on January 11, 2010. The room was previously approved by the committee in Q2-2008. The location of use exists on the facility drawings as part of the permit renewal application and thus prior approval from NHPP is not required.

Medical Events: The RSO did not receive any reports of, or identify during periodic walkthroughs or audits, any reports of circumstances that might be a medical event. This location of use did not complete any procedures for which a written directive was required.

Incidents/Spills: The RSO did not receive any reports of, or identify during periodic walkthroughs or audits, any reports of circumstances involving incidents/spills during the fourth quarter.

PET Contractual Services

New Users: There were no requests for new users during the fourth quarter.

Audits Including Security Reviews: In January of 2010, the RSO conducted an inspection for compliance with respect to security, postings and labeling. All postings were appropriate and the trailer was secure. All equipment was functional. All sealed sources were present at the time of inspection. There were minor documentation errors related to daily constancy of the ion chamber. This was due to using the incorrect calibration factor for F-18. The error using the wrong calibration factor was duly noted. There was enough evidence to support the dose calibrator was responding appropriately, and user error was based on miscommunication between the RSO for Allied and the PET technologist for Allied. In addition, sealed sources were disposed/returned to the manufacturer and all of the documentation of such transfer was not complete in the computerized system of record. This error was brought to the attention of the PET technologist for Allied and corrected immediately. The committee reviewed the report prepared by the RSO.

Medical Events: The RSO did not receive any reports of, or identify during periodic walkthroughs or audits, any reports of circumstances that might be a medical event. This location of use did not complete any procedures for which a written directive was required.

Incidents/Spills: The RSO did not receive any reports of, or identify during periodic walkthroughs or audits, any reports of circumstances involving incidents/spills during the fourth quarter.

ACTION BY COMMITTEE:

REVIEWED AND APPROVED BY UNANIMOUS VOTE THE REVISED SURVEY PROCEDURE AND THE CORRECTIVE ACTIONS TAKEN BY THE RSO AND THE SERVICE CHIEF

APPROVED BY UNANIMOUS VOTE DR. MOORE FOR 35.100, 35.200 AND 35.300 USES

6) ALARA report – Fourth Quarter CY2009

The ALARA report for the fourth quarter was submitted for committee review. The committee reviewed and approved of the fourth quarter ALARA report as written.

ACTION BY COMMITTEE:

APPROVED BY UNANIMOUS VOTE THE FOURTH QUARTER ALARA REPORT AS WRITTEN

7) Diagnostic Use of in Cardiology, Dental, Endoscopy, Radiology, Surgery & Urology

The new byplane angio system (room D318) was tested for x-ray tube performance and compliance with AAPM guidelines. Results were acceptable. Tests for shielding integrity were performed and shielding was found to be acceptable. Staff was trained on the use of the new system and the room was approved for use December 3th.

Annual testing was performed of all x-ray producing devices. All issues regarding service have been performed or are in the process of being repaired. The RSO provided the committee an interim report of all items tested. The RSO noted that not all deficiencies had been addressed. The RSO will provide the committee a final report (dates and status of repair) at the next meeting.

ACTION BY COMMITTEE:

TASK THE RSO BY UNANIMOUS VOTE TO PROVIDE REPORT ON X-RAY TUBE PERFORMANCE REPAIR AT NEXT MEETING. THIS IS ASSIGNED TRACKING NUMBER #10-03A.

8) Radiation Oncology Service

The RSO conducted an audit of Radiation Oncology Service. All reviewed records were in order. The annual calibration of the linear accelerator was performed. The RSO did not receive any reports of, or identify during periodic walkthroughs or audits, any reports of circumstances that might be an incident or misadministration.

Second Linear Accelerator Vault: A finalized design layout, shielding requirements and shielding report by Dr. Smith was forwarded to the NHPP for evaluation. All design layout and shielding assessments were performed in accordance with NHPP requirements. The final design layout does not include an escape hatch.

Audits: Two inspectors representing the American College of Radiology (ACR) inspected the service on August 17, 2009 for accreditation purposes as mandated by VACO. The committee reviewed the opening and exiting briefing minutes. A final report has been received from ACR along with an accreditation certificate.

The committee reviewed the final report. The RSO noted follow-up items for the service to address. A full report of all corrective actions taken will be provided to the committee for review when completed.

ACTION BY COMMITTEE:

TASK RADIATION ONCOLOGY SERVICE BY UNANIMOUS VOTE TO UPDATE COMMMITTEE AT NEXT MEETING WITH THE STATUS FOR CORRECTIVE ACTIONS FOR ACR ACCREDITATION INSPECTION. THIS IS ASSIGNED TRACKING NUMBER #10-03B.

9) Miscellaneous

Status report: As follow-up to the previous committee special session on January 2, 2010, the RSO informed the committee retraining for the VA Police Service regarding the change in policy to daytime only delivery of packages containing radioactive materials was completed. The AOD officers were also retrained on this policy.

In addition, the committee chair received correspondence from the Director, Mr. Maypole, approving of the actions taken to date by the committee and the RSO. An investigative report was provided to the committee chair by the Chief, VA Police Service. The committee reviewed both documents. The RSO noted NHPP will conduct a follow-up inspection in May regarding the package incident from September of 2009.

Other: A memorandum dated October 21, 2009 was issued to all Network Directors from Deputy Under Secretary for Health for Operations and Management regarding "Accountability for Safe Use of Radioactive Materials". The committee reviewed the document.

NHPP Permit: The NHPP issued an amended facility permit, Amendment No. 64 based on our response to a Severity Level III, Notice of Violation dated December 4, 2009. The committee reviewed the revised permit.

Closeouts: No closeout surveys were performed during the fourth quarter.

External Inspections: No external inspections were conducted during the fourth quarter.

Waste Shipped: No radioactive waste or sealed sources for permanent removal were shipped during the fourth quarter.

Master Materials License: The committee reviewed the most recent issues of the NHPP Newsletters, NHPP frequently asked questions (FAQs) and Information Notices issued by the NRC. The RSO informed the committee that VHA Directive 1105.01 was reviewed by at the last meeting. The RSO trained executive management on this revised directive on November 9, 2009 and the new Director in January 2010. The documents included the following.

NHPP Scatterings Special Edition, October 15, 2009
NHPP Scatterings Newsletter November/December 2009
NHPP Scatterings, Special Edition, December 22, 2009
NHPP FAQ 02-20
NHPP FAQ 01-08
NHPP FAQ 08-04
NRC Information Notice 2009-30

Footprint Management: The RSO has been reviewing the files for some time trying to reconstruct the areas where radioactive materials were used since 1952. Building 27 became the focus because it is due to have several stages of renovation over the next year. First on the list of things to change are the windows. This necessitated surveying all of the rooms previously surveyed to ensure that it meets current decommissioning standards.

As many rooms that could be surveyed in Building 27 have been completed. The other rooms that need to be tested are too full of equipment to test properly. Research Service is working with Supply Service to remove some of the equipment. In addition, Building 1 West has been resurveyed. The conducting radiation surveys that meet current decommissioning requirements has been the primary focus of the safety technician assigned to the RSO in CY2009.

The RSO provided the committee with a historical list of all areas of use currently denoted in the facility permit and deactivated rooms. The RSO noted she had included additional information in the historical list referencing other documents (survey results, architectural drawings, isotope use, etc.) that are located in the Radiation Safety Office. The Committee reviewed and approved the historical list of all areas of use.

ACTION BY COMMITTEE:

APPROVED BY UNANIMOUS VOTE THE HISTORICAL LIST OF ALL CURRENT ROOMS AND THE DEACTIVATED ROOMS OF LOCATIONS OF USE

10) Annual Review of the Radiation Safety Program for CY2009

Outside Agency Annual Requirements: As per FDA requirements, an annual summary and an individual summary for each human use research project is required to be submitted to the FDA. No subjects were studied during the course of the year, thus there were no medical events, incidents or adverse reactions noted during the year. All three open projects were closed at the request of the investigator. The annual report (membership summary and individual study summaries) was compiled and reviewed by the RSO and RDRC chairman and submitted to the FDA within the required time frame.

Annual EPA & NRC Evaluation of Effluent: As per EPA NESHAPS, an annual assessment of effluent released to the environment was performed for locations of use. The effluent released from the facilities was within the regulatory requirements for the calendar year 2009 (less than 10 mrem/yr for all isotopes and less than 3 mrem for all iodines). The RSO noted that direct measurement of breakthrough effluent was not performed since no labeling procedures were performed during the calendar year. The committee reviewed and approved the EPA NESHAPS reports provided by the RSO.

Annual Written Directives (old QMP) Evaluation: An annual assessment of all procedures requiring written directives in Nuclear Medicine service was performed by the RSO. There were no medical events during the calendar year. All records with respect to NRC, NHPP and permit requirements were in completed in accordance with departmental policy. In addition to the annual assessment, the RSO provided the committee with a list of all procedures requiring written directives over the past five years. The overall number of procedures requiring written directives continues to increase each calendar year. The committee reviewed and approved of the annual assessment provided by the RSO.

Program Review of Research Service: Overall compliance with researchers using radioactive materials is good. There were no spills in Research during the year. There were no lost packages during the year. A summary of violations occurred by research staff from 1992, through 2009 was provided by the RSO and reviewed by the committee. The RSO noted no obvious trends and overall compliance was very good. The committee approved the summary report provided by the RSO.

Annual Review of Inventory per NRC License Limits: An accurate inventory of all byproduct material is necessary in order to ensure compliance with NRC regulations. The radioactivity amounts for research and the facility are reviewed on a regular basis. The Committee reviewed an inventory summary report provided by the RSO. The RSO noted that the facility was well below the regulatory limits required in the facility's license. The RSO also noted the decrease in radioactivity inventory for Nuclear Medicine service was due to receiving unit doses instead of making their own kits and drawing doses. In addition, the RSO provided the committee with a list of all packages received to the facility during the last five years. The dramatic increase in number of packages from CY2009 to previous years was also due to unit doses. The committee approved the inventory summary report provided by the RSO.

Annual Review of ALARA Program: All personnel occupational exposures were within the regulatory limits for 2009 per NRC occupational limits. All personnel occupational exposures were within the regulatory limits for 2009 per OSHA occupational limits. Over 95% of all the exposures received by personnel were less than 500 mrem for the entire year. The committee reviewed a report prepared by the RSO that demonstrated the few individuals who received in excess of 500 mrem were clinical interventional physicians. No individual received in excess of their annual occupational exposure limit.

The RSO noted that Nuclear Medicine technologists' radiation exposures were typically the highest in the facility. This is not the case for the calendar year 2009. An assessment of their exposure was completed by the RSO comparing the previous five calendar years. Nuclear Medicine switched to unit doses, thus not as much activity is handled than previous years.

Sewer Releases of Radioactive Material per Regulatory Limits: A report of all radioactive material released via the sewer for the calendar year prepared by the RSO was provided to the committee for review. The RSO noted all releases were well within NRC and EPA regulatory limits for CY2009. The committee reviewed the report of radioactive materials released via the sewer and approved of the report provided by the RSO.

In addition, the RSO provided a report on the amounts water used by the facility uses. The RSO noted that there has a dramatic decrease in levels of usage. Upon investigation, the RSO noted it was due to changing out a water cooled chiller, thus reducing overall water usage. This energy savings had a ripple effect for determining allowable radioactive materials for sewer disposal. The RSO calculated and proposed new sewer release levels as a result of the decrease in water usage. The committee approved the CY2009 sewer release report and approved of the new sewer lease levels proposed by the RSO.

Waste Shipments: No dry solid radioactive waste was shipped as LLRW during the calendar year. Two sealed sources were transferred to another licensee during the calendar year.

Outside Reviews or Inspections:

Inspection: Paul Inspector, NHPP program manager, inspected the radiation safety program on March 10-11, 2009. This inspection included both the primary and satellite locations of use. Overall, good inspection with no violations cited.

Inspection: Two inspectors representing the American College of Radiology (ACR) inspected the service on August 17, 2009 for accreditation purposes as mandated by VACO. The Committee reviewed the opening and exiting briefing minutes. Although a final report has not yet been received, the ACR sent an accreditation certificate to the facility.

Inspection: A reactive inspection was conducted by the NHPP on October 28, 2009 in follow up to a self-reported incident where a package containing radioactive material was left unsecured and unattended in the hallway for 65 minutes on September 21, 2009. A Notice of Violation (NOV) was issued to the facility - Security violation, Level III. A follow-up inspection regarding the incident is expected in May of 2010.

Recommendations for Program Changes:

The RSO noted she will continue to stress continued efforts in security maintenance, review and heightened awareness with all staff.

The committee will continue to review fluoroscopy use, CT use, and documentation of x-ray exposure as more information becomes available from the NRSC, NHPP and the National Chief of Radiology.

Status for Security: The RSO during periodic audits and walkthroughs evaluates the status for security. A security deficiency was self-identified for a package left unattended on September 21, 2009. The RSO has confirmed the corrective actions for that deficiency and the NHPP reactive inspection.

ACTION BY COMMITTEE:

APPROVED BY UNANIMOUS VOTE ALL REPORTS (FDA, EFFLUENT, WRITTEN DIRECTIVES, ANNUAL RESEARCH REVIEW, FACILITY INVENTORY, ALARA PROGRAM, SEWER RELEASES) PROVIDED BY THE RSO

APPROVED BY UNANIMOUS VOTE TO CONTINUE TO REVIEW FLUOROSCOPY USE, CT USE, AND DOCUMENTATION OF X-RAY EXPOSURE AS MORE INFORMATION BECOMES AVAILABLE FROM THE NRSC, NHPP AND THE NATIONAL CHIEF OF RADIOLOGY

11) Pending Items

#10-03A: RSO report on x-ray tube performance and repair.

#10-03B: Radiation Oncology Service status for corrective actions for ACR accreditation inspection.

12) Documents in committee files

ALARA report
Health physics report for new uses by Dr. Applewhite
Revised radiation safety procedure for surveys in Nuclear Medicine Service
NRC forms and other documentation for Dr. Moore
Corrective action report for Dr. Morrow
ACR inspection report
VA Police Service investigation report
Annual review of radiation safety program

13) Documents in RSO files

Dosimetry reports
RSO audits for Nuclear Medicine Service, Research Service, contract PET services
10N memorandum
NHPP newsletters and FAQs
NRC Information Notice
Footprint management files with list of locations of use
RDRC files with annual report to FDA

RADIATION SAFETY COMMITTEE MEETING MINUTES
FOURTH QUARTER AND ANNUAL REVIEW Q4-CY2009

MINUTES APPROVED BY:

Chairman, Radiation Safety Committee
Ira M. Essex, M.D.

Radiation Safety Officer
Janet Frame, M.S.

MINUTES REVIEWED AND APPROVED BY:

Director
Dennis J. Maypole, FACHE

Date

MINUTES SENT TO ENVIROMENT OF CARE COMMITTEE:

Radiation Safety Officer
Janet Frame, M.S.

Date

Radiation Safety Committee audit worksheet

RADIATION SAFETY COMMITTEE AUDIT

Permittee: VA Medical Center, Anywhere (*insert date of inspection*)

Radiation Safety Committee Requirements (effective July 15, 2010)	**Yes**	**No**
Timeliness		
1. Are the minutes prepared and submitted to an internal oversight committee within 30 days after the committee meeting?		
2. Are the minutes signed and approved by the director within 45 days after the committee meeting?		
3. Are the meetings held at appropriate frequencies based on the scope of use of radioactive materials?		
Format for minutes and specific items within the minutes		
4. Is the format for the minutes consistent with standard formats in FAQ 08-04?		
5. Does the agenda include old business, new business, and standing agenda items for dosimetry, status of all procedures requiring a written directive, status of footprint management, and status for security?		
6. Do committee discussions include, as needed, new business items for reports of spills, incidents, self-identified radiation safety program deficiencies, results for external audits or inspections, and notation of committee votes?		
7. Does the tracking matrix include assigned tracking numbers and a statement of the status for items being tracked?		
8. Does the attendance matrix include a list of attendees for each meeting and document a quorum?		
9. Do the minutes include the annual review and audit report under 10 CFR 20?		
Committee files		
10. Does the facility have a single file (hard copy or electronic) with committee minutes and supporting documents?		
11. Are the committee files readily available for external review?		

Additional Comments:

VA MEDICAL CENTER
LEXINGTON, KENTUCKY

MEMORANDUM NO. 00-27
~~MARCH 18~~ DATE POSTED, 2010

RADIATION SAFETY COMMITTEE

1. PURPOSE: To delegate responsibilities and define membership of the Radiation Safety Committee (RSC) at the Lexington VA Medical Center.

2. POLICY: This VA Medical Center will have a hospital wide committee, which will oversee the radiation safety program.

3. RESPONSIBILITIES: The Radiation Safety Committee and Radiation Safety Officer function together to support the Director and take all actions necessary to ensure the safe use of radioactive materials and regulatory compliance. In the usual organizational arrangements, the Radiation Safety Officer completes day-to-day actions with oversight by the Radiation Safety Committee. Overall, the actions by the Radiation Safety Committee and Radiation Safety Officer must include, but not be limited to:

   a. Provides oversight for the safe use of radioactive materials with a focus to ensure occupational and public doses are ALARA and a safety conscious work environment is achieved.

   b. Establishes committee membership to include the Chair, Radiation Safety Officer, a management representative, a representative for each type of authorized use including Research Service, and a representative from Patient Care Services.

   c. Holds meetings that are scheduled on a recurring date during each quarter that is set by the committee. These meetings must have a quorum present of at least one-half of the committee membership and must include the Chair (or designee), Radiation Safety Officer and a management representative (or designee). If a meeting is rescheduled or canceled, meeting intervals must not exceed 6 calendar months.

   d. Prepares records and reporting committee results as required by executive management and/or Title 10 Code of Federal Regulations (CFR) 35; and ensures the records document executive management approvals for actions under 10 CFR 35 (e.g., 35.24 and 35.26).

   e. Coordinates with other medical center committees/councils (e.g., Environment of Care Council, Research committees, GEMS, Emergency Management) as needed, and reports results of committee meetings to executive management or other medical center oversight committees/councils (e.g., Environment of Care Council).

   f. Completes and/or provides oversight for the Radiation Safety Program through periodic reviews and audits, to include:

      (1) Annual radiation safety program review per 10 CFR 20.1101 to include locations of use with emphasis on decommissioning records per 10 CFR 30.

      (2) Reviews and/or audits, as needed, based on the radioactive materials scope of uses.

      (3) Evaluates results from audits, reviews, and inspections to determine possible generic issues or trends, identify root causes, specify corrective actions and actions to prevent recurrence, and determine if any results are applicable to other uses of radioactive materials.

      (4) Distributes the results of audits, reviews, and inspections to all work centers and makes available to the staff working with, or around, radioactive materials.

      (5) Oversees and follows up on resolutions of health and safety issues, and radiation safety program deviations, as needed.

g. Reviews at least every 6 months, occupational and public doses.

h. Reviews at least every 6 months, any identified health and safety issues or possible radiation safety program deviations from regulatory compliance or required practices.

i. Reviews and approves training and experience for prospective Radiation Safety Officers, authorized users, and/or other staff requiring regulatory approval.

j. Reviews and approves proposed changes to training, equipment, facilities, and radiation safety procedures or practices.

k. Ensures sealed source inventories are completed:

(1) Quarterly, for sealed sources with either current activity greater than one millicurie or current activity greater than 1000 times the quantities in 10 CFR 20, Appendix C

(2) Semiannually, for all other sealed sources, except sources specifically exempted by CFR 30.

l. Ensures sealed source records are maintained for transfer or disposition to document leak test results, if the sealed source was required by regulation or permit condition to have leak testing.

m. Provides results for sealed source inventories and leak tests to the NHPP, if requested.

n. Provides oversight for security of radioactive materials by:

(1) Compliance with regulations per 10 CFR 20.1801, 10 CFR 20.1802, and 10 CFR 37 (when issued).

(2) Prevention of adversary or unauthorized removal of radioactive materials.

(3) Compliance with the security guidelines in VHA Handbook 1200.06.

(4) Focusing on adequate security commensurate with possible risks of radioactive materials unauthorized use.

o. Classifies sealed sources, not in active use for their intended clinical or research purpose for a period of 24 months, as disused sources and evaluates the disused sources for disposal as expeditiously as possible.

p. Reviews and evaluates research protocols by:

(1) Complying with regulations per 10 CFR 35.6 for radioactive materials use in human subject research.

(2) Complying with guidelines for obtaining and documenting research informed consent as required by VHA Handbook 1200.5.

q. Uses the Nuclear Regulatory Commission documents (NUREG-1556 series) as guidance to prepare and submit requests for new, renewed, or amended permits.

r. Restricts radiation safety program implementation to be consistent with the program codes (i.e., broad-scope medical or research uses) and permits conditions approved for the permittee.

s. Ensures approvals for authorized users and locations of use (except as authorized per 10 CFR 35.14) are limited to broad-scope permittee.

t. Ensures compliance with posting requirements per 10 CFR 19 and 21.6, as in the following:

(1) VHA Radioactive Material Permit No. 16-08896-04 issued under VHA Nuclear Regulatory Commission License No. 03-23853-01VA authorizes the use of radioactive materials at this location. Contact [*current Radiation Safety Officer's name*] at [*insert current location information such as room number, mail stop, or telephone number*] to examine the permit and supporting documents.

(2) VHA license, amendments, and supporting application available for examination by contacting the NHPP at (501) 257-1571, or at mailing address NHPP (115HP/NLR), Bldg 101, Room 208, 2200 Fort Roots Drive, North Little Rock, AR 72114.

u. Provides information to workers at the various locations of use or work centers, especially satellite locations of use, on current radiation safety program and regulatory issues, as needed, using the NHPP intranet Web site, periodic newsletters, and other information resources made available to permittees.

4. PROCEDURES:

a. The Chair, Radiation Safety Committee, and Radiation Safety Officer will have stop work authority and direct access to the Director.

b ~~The minutes of each meeting will be recorded and sent to the Medical Center Director for approval through the Committee Chair and the Associate Director. After the Director's approval, the minutes will be reported to the Environment of Care Council for review.~~ The Radiation Safety Committee minutes must be prepared and submitted to the Environment of Care Council (i.e., higher-level oversight committee) for review and concurrence within 30 days after the Radiation Safety Committee meeting. The minutes must be received and signed by the Medical Center Director within 45 days after the Radiation Safety Committee meeting. The signed minutes will be distributed to the Committee members, Chair of the Environment of Care Council, Chief of Staff, Chief of Nuclear Medicine, and the ACOS/Research.

c. The Radiation Safety Committee minutes must include the following:

(1) Agenda with old business, new business, and standing agenda items listed.

(2) Standing agenda items must include:
- Summary of dosimetry results for workers
- Status of all procedures requiring a written directive
- Status of footprint management
- Status for security.

(3) New business items must include if applicable:
- Reports of spills and incidents
- Self-identified radiation safety program deficiencies
- Results for external audits or inspections.

(4) Attendance matrix or other listing of the committee members and whether a member attended an individual meeting.

(5) Tracking matrix or other listing for any unresolved items. The unresolved items must be assigned a tracking number when first identified at a committee meeting and these items tracked to closure.

(6) Summary for committee discussions and deliberations in a narrative or table format with listing or description of committee votes.

(7) The committee deliberations must include, as needed, the review and approval of authorized users, authorized locations of use, evaluation of results for audits or inspections, approval for medical or research protocols, and completion of training for radiation workers and ancillary staff.

(8) The committee minutes including additional or supporting documents used during committee meetings must be stored in a specific location in hard copy or electronic format for ease of review by external inspectors.

(9) The minutes must be maintained for the duration of the permit.

d. Membership:
Radiation Safety Officer
Member from ~~Management~~ Facility Executive Management
Member from Nuclear Medicine Service (physician, Clinical authorized user)
Member from Nuclear Medicine Service (technical staff)
Member from Patient Care Services
Member from Radiology Service (physician)
Member from Radiology Service (technical staff)
Member from Research Service (research authorized user)
Member from a clinical service involved with non-radioactive ionizing radiation (physician)
~~Member from a clinical service involved with non-radioactive ionizing radiation (technical staff)~~
NAGE ~~Safety Officer~~ union representative
(Names of actual members and appointments by the Director will be on file in the Radiation Safety Office.)

5. REFERENCES: VHA Directive 1105.1 Management of Radioactive Materials dated October 7, 2009; Title 10 Code of Federal Regulations; VHA Permit number 16-08896-04; NUREG-1556 Volumes 7, 9, and 11.

6. FOLLOW-UP RESPONSIBILITY: Chief, Radiology Service or designee.

7. RECERTIFICATION: This memorandum is due for review and recertification by ~~March 18~~ DATE MCM POSTED, 2013, in accordance with procedures in Medical Center Memorandum 001-01.

~~Sandy J. Nielsen~~ Donna K. Jacobs, FACHE
Acting Director
VAMC Lexington

Hackett, Michael

From: Hackett, Michael
Sent: Friday, May 28, 2010 11:48 AM
To: Baker, Cheryl D.; Neeley, Keith; Shih, Wei-Jen; Kiefer, Vickie; Hardin, Shannon B.; Brown, Stephen A.; Jones, Jon; Hackett, Michael
Subject: Updated MCM 00-27

Importance: High

Radiation Safety Committee (RSC) members,

Due to RSC discussion about adding another RSC member from one of the other Services that have Rad-Fluoro use (i.e., other than Radiology, e.g., Cardiology, Urology, etc.), additional changes to MCM 00-27 were needed to go along with the changes discussed during the meeting concerning new prescriptive requirements (see below) for the RSC.

The below links are to items in yesterday's agenda. MCM has been updated to reflect RSC membership changes (see copied section below or all changes via the link below) so an additional member can be added to go along with the changes to meet the new RSC requirements that were reviewed yesterday in the RSC meeting.

d. Membership:
Radiation Safety Officer
Member from ~~Management~~ Facility Executive Management
Member from Nuclear Medicine Service (physician, Clinical authorized user)
Member from Nuclear Medicine Service (technical staff)
Member from Patient Care Services
Member from Radiology Service (physician)
Member from Radiology Service (technical staff)
Member from Research Service (research authorized user)
Member from a clinical service involved with non-radioactive ionizing radiation (physician)
~~Member from a clinical service involved with non-radioactive ionizing radiation (technical staff)~~
NAGE ~~Safety Officer~~ union representative
(Names of actual members and appointments by the Director will be on file in the Radiation Safety Office.)

MCM 00-27 Update Note: ~~words being deleted~~ words being added

New Requirements: Prescriptive Requirements for the Radiation Safety

Additional Information: VHA Directive 1105.01 10.07.09

NUREG-1556 Volume 11 Section 8.7

10 CFR 33.13

10 CFR 35.24

NUREG-1516 Sections 1-4

If you have no changes/comments/etc, use the voting button above to approve the updated MCM.

Please respond by COB June 4. No response will be assumed in agreement with the updated MCM.

Thank you,
Michael Hackett, MS
Radiation Safety Officer

Tracking:

Recipient	Response
Baker, Cheryl D.	Approve: 5/28/2010 1:58 PM
Neeley, Keith	Approve: 5/30/2010 12:34 AM
Shih, Wei-Jen	
Kiefer, Vickie	Approve: 5/28/2010 1:22 PM
Hardin, Shannon B.	
Brown, Stephen A.	Approve: 6/1/2010 7:53 AM
Jones, Jon	
Hackett, Michael	Approve: 5/28/2010 12:29 PM

MANAGEMENT OF RADIOACTIVE MATERIALS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Directive establishes policies and assigns the actions to implement and maintain Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA. ***NOTE:*** *NRC issued this master materials license to VHA on March 17, 2003.*

2. SUMMARY OF MAJOR CHANGES: The major changes in this Directive incorporate focus to a safety culture, oversight for facility-level Radiation Safety Committees, and undue reliance on affiliate universities or consultants.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Office of Patient Care Services, National Health Physics Program Office (11/HP) is responsible for the contents of this Directive. Questions are to be directed to 501-257-1571 or e-mail address: vhconhpp@va.gov.

5. RESCISSIONS: VHA Directive 1105.1 dated September 22, 2004, is rescinded.

6. RECERTIFICATION: This Directive is scheduled for recertification on or before the last working day of October 2014.

Gerald M. Cross, MD, FAAFP
Acting Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publication Distribution List 10/7/09

MANAGEMENT OF RADIOACTIVE MATERIALS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policies and assigns actions to implement and maintain the Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA. ***NOTE:*** *NRC issued VHA a master materials license on March 17, 2003.*

2. BACKGROUND

a. NRC has regulatory authority for by-product radioactive materials as defined in applicable NRC regulations. Formerly, NRC issued individual licenses to Department of Veterans Affairs (VA) medical facilities to use by-product radioactive materials. Under the master materials license, VHA is authorized to issue individual permits to VA medical facilities; replacing previous NRC licenses.

b. The Under Secretary for Health is the named license official for the master materials license. The Under Secretary for Health establishes policies for the master materials license through VHA Directive 1105.01, and commitments in the master materials license application. The Under Secretary for Health provides oversight for the master materials license through the National Radiation Safety Committee (NRSC).

c. NRSC is the principal VA Central Office level organizational element to implement the master materials license. NRSC maintains and implements the master materials license through the National Health Physics Program (NHPP). NRSC operates under a committee charter and delegation of authority approved by the Under Secretary for Health.

d. NHPP directs the day-to-day implementation of the master materials license and coordinates NRSC activities. The NHPP Director is concurrently the VHA Radiation Control Program Officer and NRSC Executive Secretary.

3. POLICY: It is VHA policy to ensure the management of radioactive materials by implementing and maintaining NRC Master Materials License No. 03-23853-01VA.

4. ACTION

a. **Under Secretary for Health.** The Under Secretary for Health functions as the named master materials license official, establishes policies for the master materials license, provides a delegation of authority for the master materials license, assigns actions to implement and maintain the master materials license to achieve commitments in the license application and regulatory compliance by:

(1) Using NRC licensing and inspection criteria.

(2) Following consensus best practices for the safe use of radioactive materials.

(3) Maintaining potential exposure of ionizing radiation to workers and the public from radioactive materials to a level that is as low as reasonably achievable (ALARA).

b. **NRSC.** NRSC functions as the principal VA Central Office level organizational element to implement the master materials license. It is responsible for:

(1) Implementing and maintaining the master materials license.

(2) Completing actions under the committee charter using the delegation of authority.

(3) Providing management oversight through quarterly committee meetings.

(4) Preparing an annual report to the Under Secretary for Health based on a series of program assessments.

(5) Monitoring results of the core performance indicators.

(6) Evaluating significant programmatic actions (e.g., permitting, inspections and enforcement, response to incidents, and response to allegations).

(7) Maintaining the master materials license by periodically reviewing license policies and procedures, and if needed, submitting amendment requests for program changes to NRC.

(8) Reviewing, evaluating, and taking appropriate programmatic actions to protect worker and patient health and safety from other types of ionizing radiation, such as machine sources.

c. **NHPP Director.** The NHPP Director (the overall programmatic organizational element to implement and maintain the master materials license) who functions concurrently as the Radiation Control Program Officer for the master materials license and Executive Secretary for the NRSC, is responsible for:

(1) Serving as the principal VA Central Office level advisor on policies and procedures for the master materials license.

(2) Directing the day-to-day implementation of the master materials license, such as: permitting, inspections and enforcement, response to incidents and response to allegations.

(3) Coordinating NRSC activities under the supervision of the committee chairperson and as authorized by the delegation of authority.

(4) Developing policy and program guidelines for the master materials license and other uses of ionizing radiation.

d. **Medical Facility Directors.** Medical facility directors with a master materials license permit, function as the responsible official to ensure safe use of radioactive materials and regulatory compliance by:

(1) Establishing and implementing radiation safety practices and procedures commensurate with the radioactive materials scope of use.

(2) Providing executive management oversight to ensure protection of the health and safety of workers, the public, and environment, and to achieve regulatory compliance under the master materials license permit with a focus to a safety culture.

(3) Assigning staff with sufficient authority and resources to implement the radiation safety practices and procedures. Establishing a Radiation Safety Committee and ensuring approval and continuous coverage by a Radiation Safety Officer.

(4) Complying with master materials license permit commitments, conditions, and applicable regulations.

(5) Requiring research protocols that require the use of ionizing radiation as part of the research, be reviewed by the Radiation Safety Committee and other appropriate committees and subcommittees (e.g., Research and Development Committee, Institutional Review Board, Institutional Animal Care and Use Subcommittee, Subcommittee on Research Safety) in accordance with VHA Handbook 1200.01. ***NOTE:*** *See Section 4. e. (16) below for requirements if the research only requires the use of the results of tests using ionizing radiation that has been conducted for medical care purposes only.*

(6) Reporting to NHPP any incidents or medical events exceeding dose limits or contamination limits, unauthorized disposals or missing radioactive materials, or any significant program deficiencies.

(7) Routing amendment requests or other programmatic information to NHPP at:

National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive, Bldg 101, Room 208
North Little Rock, AR 72114

(8) Ensuring radiation workers and other workers and staff have information and assistance, as needed, to report safety concerns, engage in other protected activities, and have a safety conscious work environment.

(9) Notifying NHPP when the medical facility is inspected, or otherwise contacted by NRC.

(10) Notifying NHPP when the medical facility is contacted by an Agreement State or other regulatory authority regarding the use of radioactive materials.

(11) Avoiding undue reliance on affiliate universities or consultants.

e. **Radiation Safety Committee and Radiation Safety Officer.** The Radiation Safety Committee and Radiation Safety Officer function together to support the Director and take all actions necessary to ensure the safe use of radioactive materials and regulatory compliance. In the usual organizational arrangements, the Radiation Safety Officer completes day-to-day actions with oversight by the Radiation Safety Committee. Overall, the actions by the Radiation Safety Committee and Radiation Safety Officer must include, but not be limited to:

(1) Providing oversight for the safe use of radioactive materials with a focus to ensure occupational and public doses are ALARA and a safety conscious work environment is achieved.

(2) Establishing committee membership to include the Radiation Safety Officer, a management representative, a representative for each type of authorized use and a representative from Nursing Service.

(3) Holding meetings at intervals not to exceed 6 calendar months; and establishing a committee quorum of at least one-half of committee membership for meetings which must include the Radiation Safety Officer and management representative.

(4) Preparing records and reporting committee results as required by executive management and/or Title 10 Code of Federal Regulations (CFR), Part 35; and ensuring the records document executive management approvals for actions under 10 CFR 35 (e.g., 35.24 and 35.26).

(5) Coordinating with other medical facility committees as needed, and reporting results of committee meetings to executive management or other medical facility oversight committees.

(6) Completing or providing oversight for the radiation safety program through periodic reviews and audits, to include:

(a) Annual radiation safety program review per 10 CFR 20.1101, to include locations of use with emphasis on decommissioning records per 10 CFR 30.

(b) Reviews or audits as needed based on the radioactive materials scope of use.

(c) Evaluation of results from audits, reviews and inspections to determine possible generic issues or trends. Identify root causes, specify corrective actions and actions to prevent recurrence, and determine if any results are applicable to other uses of radioactive materials.

(d) Distribution of results of audits, reviews and inspections to all work centers and availability to the staff working with or around radioactive materials.

(e) Oversight and follow-up to resolve health and safety issues and radiation safety program deviations as needed.

(f) Evaluation of possible undue reliance on affiliate universities or consultants.

(7) Reviewing, at least every 6 months, occupational and public doses.

(8) Reviewing, at least every 6 months, any identified health and safety issues or possible radiation safety program deviations from regulatory compliance or required practices.

(9) Reviewing and approving training and experience for prospective Radiation Safety Officers, authorized users and other staff requiring regulatory approval.

(10) Reviewing and approving proposed changes to training, equipment, facilities and radiation safety procedures or practices.

(11) Ensuring sealed source inventories are completed:

(a) Quarterly, for sealed sources with either current activity greater than 1 millicurie or current activity greater than 1000 times the quantities in 10 CFR 20, Appendix C.

(b) Semiannually, for all other sealed sources except sources specifically exempted by 10 CFR 30

(12) Ensuring sealed source records are maintained for transfer or disposition to document leak test results, if the sealed source was required by regulation or permit condition to have a leak test.

(13) Providing results if requested, for sealed source inventories and leak tests to NHPP.

(14) Providing oversight for security of radioactive materials by:

(a) Compliance with regulations per 10 CFR 20.1801, 10 CFR 20.1802 and 10 CFR 37 (when issued).

(b) Prevention of adversary or unauthorized removal of radioactive materials.

(c) Compliance with the security guidelines in VHA Handbook 1200.06.

(d) Focusing on adequate security commensurate with possible risks of radioactive materials unauthorized use.

(15) Classifying sealed sources, not in active use for their intended clinical or research purpose for a period of 24 months, as disused sources and evaluating the disused sources for disposal as expeditiously as possible.

(16) Reviewing and evaluating human subject research by:

(a) Compliance with regulations per 10 CFR 35.6 for radioactive materials use in human subject research.

(b) Compliance with guidelines for obtaining and documenting research informed consent as required by VHA Handbook 1200.05.

(17) Using NRC documents (NUREG-1556 series) as guidance to prepare and submit requests for new, renewed, or amended permits.

(18) Restricting radiation safety program implementation to be consistent with the program codes (i.e., whether broad-scope or limited-scope medical or research uses) and permitting conditions approved for the permittee.

(19) Ensuring approvals for authorized users and locations of use (except as authorized per 10 CFR 35.14) are limited to broad-scope permittees.

(20) Ensuring compliance with posting requirements per 10 CFR 19 and 10 CFR 21.6, as in the following:

(a) VHA Radioactive Material Permit No. [insert specific permit number] issued under VHA NRC License No. 03-23853-01VA authorizes the use of radioactive materials at this location. Contact [insert Radiation Safety Officer name] at [insert location information such as room number, mail stop, or telephone number] to examine the permit and supporting documents.

(b) VHA license, amendments, and supporting application are available for examination by contacting NHPP at 501-257-1571, or at mailing address NHPP (115HP/NLR), Bldg 101, Room 208, 2200 Fort Roots Drive, North Little Rock, AR 72114.

(21) Providing information to workers at the various locations of use or work centers, especially satellite locations of use, on current radiation safety program and regulatory issues, as needed, using NHPP Intranet Web site, periodic newsletters, and other information resources made available to permittees.

5. REFERENCES

a. Title 10 CFR 19-21, 30-33, 35, 37 (when issued), and 71.

b. Title 49 CFR 100 to 177.5.

c. VHA Handbook 1200.01.

d. VHA Handbook 1200.05.

e. VHA Handbook 1200.06.

industrial radiography should review NUREG-1556, Volume 2, "Program-Specific Guidance About Radiography Licenses," and provide necessary information, as specified.

Response from Applicant: Describe in general terms the purposes for which the licensed material will be used.

8.7 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Executive management, the Radiation Safety Committee (RSC), if required, and the Radiation Safety Officer (RSO) and his or her staff, as necessary, work as a team to oversee the broad scope program. Each plays a critical role within its area of responsibility. The roles and responsibilities of executive management, the RSC, the RSO, and the radiation safety office staff are discussed in the sections that follow.

Note: NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," describes the role of executive management, the RSC, and the RSO at medical facilities but contains information pertinent to all broad scope programs.

8.7.1 EXECUTIVE MANAGEMENT

Regulations: 10 CFR 20.1101(c); 10 CFR 33.13(c); 10 CFR 33.14(b); and 10 CFR 33.15(c).

Criteria: The applicant must have administrative controls and provisions relating to organization and management and management review necessary to assure safe operations.

Discussion: Executive management is the individual at the senior management level who is responsible for oversight of the facility's radiation safety program and has the ultimate responsibility for the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program. NRC expects executive management to be knowledgeable of the program.

Due to the various structures of different organizations, NRC recognizes that executive management may need to delegate certain responsibilities to other managers for the day-to-day oversight of the program. For example, a large company may have several licenses issued to it for different facilities or for different activities. In this case, a company may choose to establish a senior level manager with responsibility for all of the licenses issued to that company, with the day-to-day responsibility for each license designated to the facility senior manager or program area senior manager. There are numerous ways in which an applicant may wish to structure its management oversight to meet the needs of the organization. However, there must still be one

level of management, as the licensee's representative, with ultimate responsibility for the radiation safety program.

In a Type A broad scope program, executive management or her/his delegate is a vital member of the RSC and should attend Committee meetings. In all licensed programs, executive management should be knowledgeable of the results of periodic audits and the annual review of the licensed program, to ensure all activities are in compliance with regulatory requirements and the conditions of the license, and that activities are being conducted in a safe manner. Annual reviews and audits are discussed in more detail in Section 8.10.1 of this guidance document.

The licensee should consider several factors when selecting executive management for the radiation safety program. This individual represents the highest level of facility management and has the authority to delegate resources for the program and appropriate funds in a timely manner. This individual must be available to facilitate effective and immediate action on behalf of management, the RSC (for Type A broad scope programs), and the RSO, particularly in the event of an emergency. Executive management must have the authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the regulations and conditions of the license.

Executive management is involved in selecting the chairperson and members of the RSC (for Type A broad scope) and the RSO (for Type A and Type B broad scope), and defines the role, duties and responsibilities of each. Executive management should support the RSC and the RSO, creating an atmosphere of cooperation and professionalism such that individuals feel comfortable raising radiation safety concerns. Authority will be enhanced if authorized users clearly understand that there is strong management support for, and participation in, the licensed program. Many problems can be avoided if management takes proactive steps before radiation safety problems escalate. Individuals should understand management's expectations regarding internal enforcement of program requirements and the consequences for non-compliance.

NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," Chapter 1, describes the role of executive management at medical facilities, but it also contains information pertinent to all broad scope programs.

Response from Applicant: The applicant must describe administrative controls and provisions relating to organization and management and management review necessary to assure safe operations. It is recommended that the applicant submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the RSC (for Type A broad scope), and the RSO (For Type A and Type B broad scope).

8.7.2 RADIATION SAFETY COMMITTEE

Regulations: 10 CFR 33.13(c)(1) and 33.13(c)(3)(iii).

Criteria: Type A broad scope licensees must establish a Radiation Safety Committee (RSC), which works with executive management and the Radiation Safety Officer (RSO) in implementing the radiation safety program. Type B and Type C broad scope licensees are not required to establish an RSC.

Discussion: An applicant for a Type A broad scope license must establish a RSC pursuant to 10 CFR 33.13(c)(1). The RSC works with executive management and the RSO in implementing the radiation safety program, and will be involved in establishing policies and procedures for managing the radiation safety program. The RSC, through the executive management, must have the authority and flexibility necessary so that it may effectively fulfill its role in managing the radiation safety program.

The RSC for a Type A broad scope program is composed of such persons as the RSO, executive management, and persons trained and experienced in the safe use of byproduct materials. Each area of use under the license should be represented on the RSC.

A chairperson for the committee should be selected. There are several factors to consider when selecting a chairperson for the RSC. An individual with a knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of their position within the facility, and a desire to serve as chairperson will facilitate the effectiveness of the RSC. Additionally, the individual chosen as the chairperson must have the time to devote to the position in addition to other responsibilities he or she might have within the facility. Executive management should delegate a level of authority to the position so that the chairperson is effective. In general, the RSO should not be appointed as the chairperson of the Committee, since the RSO is responsible for the day-to-day operation of the radiation safety program and may be too closely involved with the licensed activities to be objective.

The RSC should establish a quorum for RSC meetings. A quorum consisting of the chairperson of the committee (or his/her designee), the RSO, the executive management (or his/her alternate), a representative from each area of use from which specific issues will be discussed, and any other member whose field of expertise is necessary for the discussion is considered acceptable.

The meeting frequency for RSC meetings for broad scope programs is not specified in 10 CFR Part 33. The RSC should meet as often as needed to ensure the radiation safety program is operating in compliance with the license, established procedures and the regulations. For most programs, quarterly RSC meetings are needed to adequately oversee the program.

The RSC should maintain minutes of its meetings. The minutes should include the date of the meeting, the members present and absent to demonstrate a quorum was present, a summary of the discussions, recommendations and the results of votes. The RSC should also document its review of new users, uses, and program changes. The minutes should also include information related to the ALARA program reviews and the annual audit review.

Duties and Responsibilities

The committee is responsible for reviewing personnel dosimetry data, discussing the results of required radiation surveys, and any significant incidents, including spills, contamination, misadministrations, etc. The RSC is also required to review the program for maintaining doses ALARA and providing any necessary recommendations to ensure doses are ALARA. The overall compliance status for authorized users should be thoroughly reviewed. The RSC, working with the executive management, shares responsibility with the RSO for conducting periodic audits of the radiation safety program. Additionally, the Committee reviews any consultant's audit findings and acts upon those findings. The RSC also reviews the results of the annual audit of the radiation safety program. Possible trends should be analyzed, and suggestions for timely and corrective action should be made. Problems should be clearly defined and reviewed in the future as open items. An assessment of the effectiveness of corrective actions is also helpful in deterring or eliminating future problems and violations.

One of the primary responsibilities of the RSC for a broad scope program is to evaluate new users and new uses of byproduct material. The RSC needs to consider all available information in making decisions. This includes evaluating the training and experience of applicants who request authorization to use radioactive material at the facility, using criteria developed by the RSC. The RSC members should be aware of the regulatory training and experience criteria that apply to each type of use at their institution. For example, 10 CFR Part 35 contains the training and experience required for authorized users in medical programs. The criteria developed by the committee should include such things as the requester's training and experience, the proposed facilities, the protocol for using radioactive material to ensure that all procedures are in accordance with good radiation safety practices, and waste disposal.

For Type A broad scope licensees or applicants for a Type A broad scope license who desire the flexibility to make certain program changes and changes to certain procedures as discussed in Section 1 of this document, the RSC, along with executive management and the RSO, will review and approve program and procedural changes in accordance with criteria developed and approved by the RSC. The criteria for reviewing and approving such changes should include provisions for training staff before implementing new procedures and ensure that the proposed changes will not degrade the effectiveness of the currently approved program. Additionally, the audit program should include an evaluation process that will assure that changes have been properly implemented by the staff and will determine the effectiveness of changes made in achieving program goals.

NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," Chapter 2, describes the role of the radiation safety committee at medical facilities, but contains information pertinent to all broad scope programs.

For medical broad scope programs, the requirements of 10 CFR Part 35 must be met. Broad scope licensees should review other base NUREGs that may apply to their licensed program,

such as NUREG-1556,Volume 9, "Program Specific Guidance About Medical Use Licenses," for licensees who possess radioactive material for medical use.

Response from Applicant: Applicants for a Type A broad scope license should submit the following:

- Description of the duties and responsibilities of the RSC.
- Criteria used for selecting members of the RSC, including what members and the number of members constituting a quorum. Members should be indicated by position title, rather than by name.
- Criteria used by the RSC and RSO for approving new users and new uses.

In addition, applicants for a Type A broad scope license who are requesting the flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license should submit the following:

- A description of the duties and responsibilities of the RSC, including:
  - — review and approval of permitted program and procedural changes prior to implementation;
  - — implementation of program and procedural changes;
  - — audit of licensed operations to determine compliance; and
  - — taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

- A description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.

8.7.3 RADIATION SAFETY OFFICER

Regulations: 10 CFR 30.33(a)(3); 10 CFR 33.13(c)(2); 10 CFR 33.14(b)(1); 10 CFR 34.42; 10 CFR 35.21; and 10 CFR 36.13(d).

Criteria: Type A and Type B broad scope licensees must have a Radiation Safety Officer (RSO) who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters. The RSO's training and experience must include the types and quantities of licensed material to be authorized on the license. While

regulation does not require Type C broad scope licensees to have an RSO, 10 CFR 33.15 requires that the licensee establish administrative controls and provisions relating to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. Type C broad scope licensee management should appoint someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

Discussion: Each Type A and Type B program in which byproduct materials are used must appoint an RSO who is responsible for radiation safety and compliance with the regulations for the use of byproduct material. Each Type C broad scope program should appoint an individual who is responsible for the day-to-day operation of the radiation safety program. In a Type A broad scope license the RSO is a member of the RSC and works closely with the RSC and executive management in implementing the radiation safety program. The RSO must ensure that radiation safety activities are being performed safely according to approved policies and procedures, and that all regulatory requirements are met. The RSO should have full access to all activities involving the use of byproduct material and the authority to terminate any activity in which health and safety appear to be compromised without consulting with executive management or the RSC, if required. The applicant should submit a "Radiation Safety Officer Delegation of Authority" signed by executive management. Appendix J contains a model "Delegation of Authority" that is acceptable to NRC.

In a Type A broad scope licensed program, the RSO typically performs a preliminary review of proposed new uses and users, prior to formally discussing the proposal with the RSC. The RSC grants the formal approval of new users and uses in a Type A broad scope license. The task of reviewing and approving proposed uses and users in a Type B broad scope licensed program is the responsibility of the RSO. In a Type C broad scope program, individuals are qualified as users if they meet the training and experience criteria described in 10 CFR 33.15(b). While no licensee Committee or individual is required by regulation to make the determination that an individual is qualified to use the material possessed under the Type C broad scope license, or that a particular use of byproduct material is safe, licensee management is ultimately responsible for assuring safe operations.

The RSO performs audits of all areas of use and individuals who are authorized to use byproduct material to ensure work is done in accordance with the license, regulations, and user permit conditions. Specific duties and responsibilities of the RSO include:

- Monitoring and surveys of all areas in which radioactive material is used
- Oversight of ordering, receipt, surveys, and delivery of byproduct material
- Packaging, labeling, surveys, etc., of all shipments of byproduct material leaving the institution

- Personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits
- Training of all personnel
- Waste disposal program
- Inventory and leak tests of sealed sources
- Decontamination
- Investigating any incidents and responding to any emergencies
- Maintaining all required records.

The responsibilities of the RSO may not be transferred to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals; however, the responsibility for these tasks and duties is with the RSO. NRC does recognize that a qualified individual will have to fill in for the RSO when the RSO will be away for short periods of time for professional conferences, vacation, or illness. However, this should not occur for extended or indefinite periods of time. Consideration should also be given to how this individual would be contacted in the event of an emergency.

When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position, select an individual who is qualified to serve as the RSO. The RSO will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with byproduct materials under his or her responsibility. NRC recognizes that an RSO cannot be an expert in all areas that might be involved in a broad scope program. The RSO should be qualified by training and experience to perform the duties required for the position. Executive management should ensure that enough time is allocated to the individual selected as the RSO to carry out the responsibilities of the position.

The applicant should review the Radiation Safety Officer guidance provided in the base NUREG corresponding to the particular type of licensed program. For example, NUREG-1556, Volume 7, "Program Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," contains guidance that is appropriate for broad scope licensees who are involved in research and development.

The applicant should also be aware of specific regulatory requirements for the RSO which may apply to their licensed program. For example, 10 CFR Part 35 contains specific requirements for an RSO in a medical program. However, an individual who qualifies as a medical RSO is not necessarily qualified to be RSO in a broad scope program.

Chapters 3 and 4 of NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," describes the role of the RSO and selection of the RSO at medical facilities but it also contains information pertinent to all broad scope programs.

Response from Applicant:

For Type A and Type B Applicants:

- Submit the name of the proposed RSO
- Describe the training and experience for the proposed RSO that demonstrates the individual is qualified to perform the duties required under the license
- Submit a statement delineating the RSO's duties and responsibilities
- Submit a Radiation Safety Officer Delegation of Authority signed by the licensee's executive management.

For Type B Applicants, submit the criteria used by the RSO to approve of new users and uses of byproduct material.

For Type C Applicants, submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program, e.g., the RSO, who will be contacted if there are further questions about this application, and who is duly authorized to act for the applicant or licensee, as required by 10 CFR 30.32(c).

Applicants should provide specific information about the proposed RSO's training and experience which is relative to the licensed material requested in the application. Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, etc. This only serves to slow down the review process.

Note: It is important to notify NRC, as soon as possible, typically within 30 days, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to NRC as part of an amendment request. Applicants should review the regulations for specific program areas, such as medical uses, that have specific requirements regarding changes in the RSO.

8.7.4 RADIATION SAFETY OFFICE STAFF

Criteria: Licensees should provide sufficient staff to assist the Radiation Safety Officer in implementing the radiation safety program.

Discussion: The licensee should provide the RSO with a sufficient staff of professional and administrative support personnel. The number of staff and their qualifications will vary depending on the scope of the program. For small programs, the RSO may not require any assistance. Licensees should evaluate the licensed program and ensure that the RSO has adequate resources to effectively manage the program.

Chapters 6 and 7 of NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," discusses the subjects of radiation safety program resources and the use of consultants and service companies at medical facilities, but contains information pertinent to all broad scope programs.

Response from Applicant: No response is required.

8.8 ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO OCCUPATIONAL WORKERS AND ANCILLARY PERSONNEL)

Regulations: 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 30.33(a)(3); and 10 CFR 30.34(e).

Criteria: Before beginning work with or in the vicinity of licensed material, all individuals who are likely to receive an occupational dose in excess of 1 mSv (100 mrem) in a year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training.

Discussion: 10 CFR 19.12(a) describes the training that licensees are required to provide individuals who, in the course of their employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). 10 CFR 19.12(b) requires that the licensee, in determining which individuals are subject to the training requirements of 19.12(a), consider assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during the life of a licensed facility. While many licensees can demonstrate that it is not likely during a normal situation for a laboratory worker, manufacturing technician, hospital technologist, or environmental services worker at their facility to receive in a year an occupational dose in excess of 1 mSv (100 mrem), these individuals and others could reasonably be expected to receive this level of exposure during abnormal situations (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Practical, site-specific training should be provided for all

§ 33.13 Requirements for the issuance of a Type A specific license of broad scope.

An application for a Type A specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant has engaged in a reasonable number of activities involving the use of byproduct material; and

(c) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations, including:

(1) The establishment of a radiation safety committee composed of such persons as a radiological safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials;

(2) The appointment of a radiological safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters; and

(3) The establishment of appropriate administrative procedures to assure:

(i) Control of procurement and use of byproduct material;

(ii) Completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(iii) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with paragraph (c)(3)(ii) of this section prior to use of the byproduct material.

Subpart B--General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing--

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to--

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

1 ROLE OF EXECUTIVE MANAGEMENT

1.1 Introduction

This chapter offers guidance to executive management of a licensed medical facility on executive management's role in effective implementation and management of the radiation safety program. For the purposes of this report, the term "executive management" refers to an individual at the senior vice-president or chief executive officer level who is responsible for oversight of the facility's radiation safety program. In a broad scope program, this individual could be a senior administrator, whereas, in a small licensed program, this individual could be the sole owner and operator. Regardless of the individual's title, the NRC expects executive management to appoint a representative who actively participates as a member of the radiation safety committee (RSC) and has the authority to delegate necessary resources to the radiation safety program, as identified by the RSC. The term "executive management" does not include department managers in radiology, nuclear medicine, radiation oncology, or any other department of the facility, regardless of department size.

Executive management should become familiar with the types of radiation sources used at the facility, and where they are used, received, and stored. This is particularly important since some medical uses pose a higher safety risk than others for occupational workers, patients, and the public. For example, radiation therapy presents a higher risk than diagnostic radiology or nuclear medicine applications. Specifically, sealed radiation sources and linear accelerators for in-patient and out-patient radiation therapy procedures pose a potentially significant safety hazard because of the higher radiation levels associated with the use of these devices. In order to fully appreciate these medical use areas, executive management should consult with individuals expert in these areas, such as authorized physician users or health or medical physicists, to ensure that adequate resources are provided for the radiation safety program, including support for the radiation safety officer (RSO) and the RSC. See Chapter 6 for further discussion on radiation safety program resources.

1.2 The Management Triangle

The "management triangle," a concept used throughout this report, comprises three elements: executive management, the RSO, and the RSC. The concept was developed for the purposes of this report to emphasize that there are three primary responsible entities for radiation safety program management. No one element is considered more important than the others; rather, the management triangle represents a team approach in which the success of the team is dependent upon the contribution of each element. Each element of the management triangle is discussed in a separate chapter to emphasize its respective role, relationship with the other elements, and the need for effective communication between elements to establish and maintain an effective management team (Chapters 1, 2, and 3). Even though all elements are considered equally important, it should be noted that NRC regulations specify that executive management of the licensed facility has ultimate responsibility for the radiation safety program, even though executive management may depend heavily upon the RSO and RSC. This means that even though the RSC and, in particular, the RSO, oversee the day-to-day operations of the program, and are the informed bodies to which executive management turns for information, the license is issued to the institution (executive management) and executive management of that institution is held responsible for implementing the licensed program.

Figure 1: Management Triangle (Emphasis on Executive Management)

In addition to the three elements of the triangle, it is recognized that other individuals augment the management triangle and are responsible for many aspects of the day-to-day operations within a radiation safety program. Among these individuals are authorized users including physicians, supervised nuclear medicine and radiation therapy technologists, pharmacists, physicists, nursing staff, radiation safety staff, other allied health care personnel, consultants, and contractual service companies. In Chapter 5, the staff discusses the role of facility personnel, and Chapter 7 discusses the use of consultants and service companies.

The Management Triangle Without the RSC

NRC requires all medical facilities that meet its definition of a "medical institution" to establish an RSC. Licensed facilities that do not meet this definition are only required to have an RSO, who assists executive management in the oversight of the licensed program. Examples of programs that may not meet the definition of medical institution include some private or group physician practices, freestanding clinics, or mobile nuclear medicine services. The national health care delivery system is evolving and the number of medical facilities and number of services offered per facility are changing. As a result, regulatory agencies should reevaluate licensed programs that grow significantly, such as an increase in the number of medical disciplines practiced or number of authorized users, to determine whether additional regulatory requirements should apply to ensure an adequate level of radiation protection for facility workers and members of the public. Therefore, a licensed program that has historically not been required to have an RSC may become subject to this requirement on the basis of growth.

In medical facilities without an RSC, the role of executive management may actually be greater on a day-to-day basis, than in programs that have an RSC, since the responsibility for oversight of the licensed program is shared only with the RSO. Also, in the practices of some private physicians, executive management may be limited to one individual who is also the sole owner, sole authorized user, and RSO. In this case, the executive management–RSO would be the sole individual responsible for the radiation safety program. Regardless of whether there is an RSC or whether another individual is authorized as RSO, executive management should be knowledgeable of its responsibilities and should support the day-to-day operations of the program.

1.3 Selecting the Executive Management Representative to the RSC

Careful consideration of who will be selected to represent executive management and oversee the radiation safety program is a high priority when developing a program, or reassigning this responsibility. This individual represents the highest level of facility management and should have authority to delegate resources for the radiation safety program, as identified by the RSC. Additionally, executive managers should become knowledgeable of their role, the roles of the RSC and RSO, and their interrelationship. The radiation safety program may have significant financial needs and the executive manager should have authority to appropriate funds in a timely manner. In addition, the radiation safety program at the facility often involves several departments; therefore, the manager should have broad responsibilities and authority, and should have the ability to negotiate the needs of various parties. Although uncommon among licensees, it may be beneficial if the executive management representative has a science background or an aptitude for radiation safety issues.

The designated management representative should be available to the RSO and RSC

chairperson and should not be buried in a chain of command that does not facilitate effective and immediate action on behalf of management or the RSO and RSC in the event of a radiation safety emergency or potential emergency. In other words, the RSC chairperson and RSO should have access to and a direct line of communication with executive management to discuss radiation safety issues that need to be brought to management's attention. Additionally, the executive management representative should have the authority to make prompt decisions on the basis of the information available without having to consult with higher management officials.

1.4 Executive Management's Relationship With the RSO and RSC

1.4.1 Management Support for the RSO's Authority

The RSO has primary responsibility for maintaining the radiation safety program on a day-to-day basis; therefore, selecting the RSO for a new program or replacing the RSO in an existing one should be carefully considered. Chapter 4 is dedicated to this issue. When establishing or redefining the role of the RSO, executive management should clearly define the authority delegated to the RSO from executive management. In 10 CFR Part 35, NRC requires its licensees to submit a written statement detailing the authorities, duties, and responsibilities of the RSO. Therefore, the delegation of authority to the RSO should be discussed with the RSC to ensure that ample authority has been bestowed, and that the RSO has the necessary latitude to ensure implementation of an effective radiation safety program. In a radiation emergency or a potential emergency during which health and safety may be jeopardized, the RSO should be given ample authority to resolve the situation immediately. Specifically, the RSO should have authority to immediately terminate an unsafe practice or work activity with unchallenged authority and without prior coordination with the RSC or licensee management. This authorization should include unhampered access to all human uses of, and research projects utilizing, radioactive material.

The RSO should also have the authority to suspend or cease operations that are not in full compliance with safety regulations or license commitments. To support the RSO in these actions, management should not create a real or implied consent which permits some individuals at the facility to circumvent radiation safety requirements. Violators of the institution's radiation safety requirements should be aware of management's support for internal enforcement, which may include suspension of user authorizations. However, an authorized user, whose authorization has been suspended or revoked, should have the opportunity to appeal to the RSC a decision made solely by the RSO.

Executive management should ensure that the RSO has adequate time to fulfill the role. Depending upon the size and scope of the licensed program, the RSO's job could be a part-time or full-time commitment. If the job of the RSO is a full-time commitment, it may be difficult if not impossible for the RSO to be involved with or responsible for patient therapy procedures, some of which demand considerable time. Therefore, management, with assistance from the RSC, should accurately estimate time requirements associated with program management, delegate the necessary authority to the RSO, and demonstrate support for the RSO to fulfill the role. Without management's support, the RSO may not be effective.

On occasion, the RSO will be absent for a period of time and there will be a need to identify a qualified individual to carry out the responsibilities of the RSO. This typically occurs when the RSO is absent because of illness, vacation, work travel, holidays, and the like. However, the substitute cannot fulfill the role of RSO for an extended period of time without seeking prior approval by the regulatory agency. Usually, the RSC, in coordination with executive management, determines who will temporarily be responsible for acting as RSO. It is important that executive management delegate an appropriate level of authority to this individual so that the person can act effectively. Also, management should ensure that the individual filling in for the RSO has adequate time to perform all the duties and tasks of the RSO. Other assigned duties may

need to be reassigned until the RSO returns and the replacement individual returns to his/her position. Generally, the practice of identifying an individual to temporarily replace the RSO is permitted by regulatory agencies; however, it should be noted that, under NRC regulations, only one person can be authorized and responsible as the RSO. Therefore, RSO *duties* can be delegated to other qualified individual(s) on a permanent or temporary basis, but the *responsibilities* of the RSO cannot be delegated. See Chapter 3, "Role of the Radiation Safety Officer," for further discussion on delegation of RSO tasks and duties.

1.4.2 Management's Support for RSC's Authority

Management should empower RSCs to conduct their official duties and responsibilities and exercise authority in accordance with regulatory requirements, including those described in the license application. Similar to what is required of RSOs, NRC requires its licensees to submit in writing the authorities, duties, and responsibilities of the RSC. Management should delegate an appropriate level of authority to the RSC to enable the committee to fulfill its role as part of the management team. After all, the RSC serves as a collegial consensus and resource for executive management and is responsible for most, if not all, decisions that affect the radiation safety program. RSC duties include, but are not limited to, the review of the licensed as low as reasonably achievable (ALARA) program to ensure radiation exposure levels at the facility are within acceptable limits; review of training and experience documentation submitted by proposed authorized users, RSOs, and medical physicists; approval of policies and procedures; review of radiation exposure dosimetry records; investigation of incidents involving licensed material; review of the annual audit of the radiation safety program; and enforcement of decisions made by the RSC. Since the RSC membership is composed of a cross-section of departments that use radioactive material, their input and decisions are valuable and serve as a collegial consensus for facility personnel and management. In Chapter 2, the staff describes the role of the RSC, its duties and responsibilities, and its relationship with executive management and the RSO.

1.4.3 Communication With the RSO and RSC

Once the radiation safety program management "triangle" has been established, effective and periodic communication between all elements in each direction is essential. Poor communication between one or more elements can lead to a weak radiation safety program and can result in an overall lack of adequate oversight. This is particularly true when one element leaves the majority of the responsibility to the other two elements, and does not routinely communicate its concerns, questions, or information regarding the program. If the RSC is not as active as it should be, executive management may not be aware of program resource needs. As a result, management may not appropriate adequate resources and the RSO could find it difficult, if not impossible, to implement and maintain the radiation safety program. Good communication among the three components of the triangle requires conversation and periodic meetings, either formal or informal, both of which may need to be followed up in writing so that agreements are confirmed and all individuals are fully aware of their responsibilities and associated time limits.

1.4.4 Management Attendance at and Participation in RSC Meetings

Under the leadership of the RSC chairperson and the RSO, RSC meetings should be conducted periodically to discuss radiation safety issues at the medical facility. It is essential that all required members attend and, in particular, that the executive management representative of NRC-licensed facilities attends. To establish a quorum, the regulations require that at least half of the members be present, including the RSO and executive management representative (10 CFR 35.22(a)(3)). If the designated executive management representative is unable to attend or to send an alternate, the meeting could be held but it should not be counted as one of the required periodic meetings. Regulatory agencies recognize that, from time to time, the executive management representative will be unavailable at

the last minute to attend, and it may be necessary to have an alternate attend in order to transmit information. This practice is considered acceptable if it occurs infrequently. However, if it becomes more frequent or routine, the RSC should bring this issue to the attention of a higher management official to ensure that the radiation safety program receives the support it needs from licensee management. This is necessary to ensure that the overall performance and effectiveness of the committee is not impaired. Additionally, executive management should be cognizant of all required RSC members and should be aware of members who are routinely absent, since this may indicate someone who is reluctant to participate. In that case, executive management may need to recommend to the RSC that such members be replaced.

Active participation in the RSC by executive management sends a strong message to the RSC, the RSO, authorized users, and other individuals involved with or responsible for the radiation safety program. In addition, management involvement is essential when the institution is undergoing rapid change, a reorganization, or restructuring. Problems can occur when executive management does not take a proactive approach until radiation safety or related administrative problems escalate. Therefore, it is in management's best interest to gather information on the magnitude of the radiation safety program and its needs because executive management is ultimately responsible and provides necessary resources for the program.

1.4.5 Assessing RSO and RSC Performance

NRC or Agreement State* inspectors perform regulatory assessments for compliance. However, executive management should not rely on regulatory inspections alone to assess overall performance of the RSC, the RSO, and the radiation safety program. Regulatory agencies expect licensees and, in particular, executive management to periodically perform self-evaluations of the radiation safety program and to take action on identified problems. Therefore, by performing the assessments discussed below and the audits described in Chapter 8 of this report, management will be able to meet this challenge.

Parts 20 and 35 of 10 CFR require NRC licensees to periodically (at least annually) review the radiation protection program content and implementation. Additionally, for NRC licensees who have committed to Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Appendix G, executive management should evaluate the implementation of the radiation safety program annually. A meaningful evaluation to meet these commitments requires assessing RSO and RSC performance by reviewing technical program achievements, regulatory compliance, and relationships with authorized users of radioactive material. It is recognized that executive management may not have the knowledge or resources to perform this assessment; therefore, from time to time, executive management may need to rely on outside assistance or to utilize technically qualified persons within the medical institution to make this assessment. Obviously, individuals within the licensed facility may find it difficult to be completely objective or may lack sufficient knowledge to make a comprehensive assessment. Qualified health-physics consultants and RSOs from other medical facilities could perform independent assessments and may provide meaningful insight into other programs. An exchange program could be established whereby similar facilities conduct periodic audits of each program in an effort to identify deficiencies, potential violations, and health and safety issues. Peer audits can be effective when conducted in an open, non-threatening manner for the purpose of improving the program through constructive criticism. It should be emphasized that the idea of utilizing an external auditor to conduct the required management audit of the radiation safety program is not an NRC requirement; rather, the idea is presented as a possible management tool to assess the RSO's and RSC's performance.

As part of conducting a management audit of the radiation safety program, management should determine whether the RSO and RSC chairperson work well together and with others who are responsible for the safe use of licensed material.

*See Appendix A for a directory of Agreement States.

The RSO, the RSC chairperson, and authorized users should work cooperatively for the program to succeed and for the RSO to enforce radiation safety program policy. Executive management should address situations in which an authorized user is able to exert influence over radiation safety enforcement by virtue of title, rank, or reputation by demonstrating support for the RSO when the RSO is unnecessarily challenged. As a result of such support, individuals will be more likely to comply and the RSO will be more effective. For such a balance to exist, it is imperative that all three elements of the management triangle support this philosophy.

1.5 Deciding Whether To Use Consultants or Service Companies

Utilizing the services of qualified consultants and service companies (collectively, "contractors") is a decision to be made by each licensee. The practice is generally neither discouraged nor encouraged by regulatory agencies. Contractors can provide valuable services which enhance the quality of a radiation safety program. Most licensees contract for such services as survey instrument calibration, sealed source leak testing, and personnel dosimetry. In Chapter 7, "Use of Consultants and Service Companies," the staff discusses the types and roles of contractors, contractual arrangements, and issues associated with the use of contractual support. It is important that executive management note that a contractor's findings should always be reviewed by the RSO, the RSC, and executive management for completeness and accuracy. In addition, regulatory agencies hold the licensee, not the consultant, responsible in instances in which the consultant fails to identify a safety problem or regulatory violation, or when the licensee fails to follow up on an issue or violation identified by the consultant.

1.6 Conduct of Required Audits

Executive management is responsible for ensuring that the radiation safety program is audited as required by the regulatory agency. Most regulatory agencies require periodic audits of certain aspects of the program, such as personnel radiation exposure records, to ensure adequate protection of public health and safety and regulatory compliance. One type of required audit, the "management" audit was briefly discussed earlier in this chapter when describing how to assess RSO and RSC performance. Audit feedback mechanisms are an effective management tool for the radiation safety program and provide regulatory agencies with information regarding implementation of a radiation safety program. In Chapter 8, "Conduct of Audits," the staff discusses all required audits in greater detail.

1.7 Enforcing Radiation Safety Policy

Executive management should be committed to assisting the RSC and RSO in resolving cases where individuals have violated internal radiation safety polices or procedures, or regulatory commitments. In many cases, the final official decision for corrective action will require support by the RSO and RSC, and may require a final decision by executive management. This decision should be based on a fair and impartial review by the RSO and RSC where all affected and interested parties have had their opportunity to present relevant information. Executive management should never allow an individual's influence or status to overrule the RSC's or RSO's decisions, or alter the decision process. To permit this would severely compromise the radiation safety program and make a mockery out of the authority of the RSO and RSC. Also, such biased actions by management could be construed as wilfully condoning violations of radiation safety requirements.

1.8 Summary

Executive management, even though assisted by the RSO and RSC, is ultimately responsible for the radiation safety program. Executive management should delegate an appropriate level of authority to, and demonstrate support for, the RSO and RSC for decisions that affect the licensed program. The RSO and RSC may find it difficult, if not impossible, to fulfill their responsibilities in the absence of executive management support. Radiation safety programs require such resources as space, equipment, personnel, time, and possibly contractors.

Therefore, executive management should assess these needs to ensure that adequate resources are continously provided. Equally important is the need to create an environment that promotes and facilitates effective communication and oversight. Since no two facilities are exactly alike, this report cannot describe the ideal or perfect organizational chart to facilitate effective management in each licensed facility. However, the necessary tools have been briefly described. In developing a facility-specific program, it is important to be open to alternatives for establishing an effective oversight program which may include untraditional organizational charts, the use of contractors to perform radiation safety program audits, delegation of specific duties to individuals, and an "exchange" program with a facility of similar size and scope for performing independent evaluations of the radiation saety program.

2 ROLE OF THE RADIATION SAFETY COMMITTEE

2.1 Introduction

This chapter discusses the responsibilities of the RSC, including selecting committee members and conducting meetings, and the RSC's relationship to the two other elements of the management triangle: the RSO and executive management. As discussed in Chapter 1, medical facilities that constitute a medical institution should establish an RSC to oversee the radiation safety program with the assistance of the RSO. The RSC represents a cross-section of medical use areas, expertise, and management, and serves as an effective collegial group to develop and promote a quality radiation safety program.

Figure 2: Management Triangle (Emphasis on the RSC)

2.2 RSC Support to Executive Management

The RSC functions to provide guidance and information on the radiation safety program to executive management, ensure that adequate resources are provided by licensee management, and assist the RSO in the development, implementation, and maintenance of the radiation safety program. The RSC serves as a "window" to the licensed program through which management gains an overall picture of its activities, and the respective roles of the RSO, RSC, and other responsible individuals, including authorized users. The RSC should ensure that executive management is periodically given all relevant information regarding the radiation safety program, particularly when management will make decisions that may affect the program. After careful deliberation and collective decision-making between management and the RSC, the RSC (including the RSO) should support and implement the final management decision. In order for other individuals at the licensed facility to support the final decision, they must observe that the management team reviewed all relative information and arrived at a consensus. Without such support from individuals working with licensed material on a daily basis, the management team will be ineffective.

2.3 Selecting an RSC Chairperson and RSC Members

2.3.1 Selecting the RSC Chairperson

The knowledge and leadership abilities of the RSC chairperson will promote the effectiveness of the RSC. Thus, selection of the RSC chairperson is an important task for executive management and other RSC members if an RSC exists. Some qualified individuals at the facility would prefer not to assume the role for various reasons, and these people should not be coerced since a reluctant individual could presage an inactive chairperson and an inactive committee. Another important consideration is whether the prospective candidate has adequate time to devote to the RSC chairperson position in addition to other job responsibilities or assignments. An effective RSC usually has as its head someone who wants the position, is knowledgeable, and has leadership skills and adequate time to devote to accomplishing the goals of the RSC and fulfilling the role of chairperson.

Although often convenient, management should be cautious when appointing the RSO to chair the RSC for several reasons. First, the RSO is responsible for the day-to-day operations of the radiation safety program and may be too closely involved with licensed activities to be objective. Secondly, depending on the scope of the licensed program, the time necessary to carry out the responsibilities as RSO and complete other

assigned duties associated with patient care may absorb all of that individual's time. Third, the chairperson represents an extension of facility management should a disagreement arise between the RSO and an authorized user, or with any individual involved with licensed material, making such issues difficult to resolve if the RSO is the chairperson. Finally, filling the chair with the RSO is not consistent with the management triangle at medical institutions, since the role of the RSO is to provide technical expertise to the RSC and executive management. Regulatory agencies have observed difficulties in programs in which the RSO is also the RSC chairperson. The committee and its chairperson represent executive management in the formulation of policy for the radiation safety program; therefore, the chairperson is expected to guide the committee's agenda. Frequently, the best radiation safety policy for the institution is not the easiest for the RSO to implement; thus, conflicts of interest may arise when the RSO is chairperson. Also, because the committee is expected to hear users' grievances against audit findings, it is inappropriate for the RSO to be the most prominent member of the committee. Furthermore, among the responsibilities of the RSC is the auditing of the radiation safety office in the performance of its duties. Again, this makes it difficult and inappropriate for the RSO to be the most prominent member of the committee.

Some medical institutions appoint an authorized physician user as the RSC chairperson. Authorized users can effectively head the RSC since they are knowledgeable of the medical application of licensed material, have requisite authority and credibility, and access to executive management. However, problems can occur when the chairperson is an authorized user who is the principal large user, since a conflict of interest could occur in certain situations involving licensed material and the radiation safety program. The RSC could develop internal procedures to avoid this situation. Also, it could be difficult for the authorized user-chairperson to be effective since physicians are typically not employees of the medical facility and, as a result, may be limited in their authority to impart or enforce decisions. For other users, such as researchers or principal investigators, to be designated as chairperson, executive management should delegate an appropriate level of authority to the position so that the chairperson is effective, particularly in situations where decisions will affect other departments or areas in the facility.

In some licensed programs, a medical physicist assumes the role of RSC chairperson. This can be an effective choice since a qualified medical physicist has a more than adequate knowledge of radiation and issues related to radiation safety. Additionally, in many cases, the physicist has responsibility for, and hands-on involvement with, those types of radioactive material at the licensed facility that pose the greatest hazard to patients, workers, and the public, that is, sealed sources used for teletherapy and brachytherapy. Like the researcher or principal investigator, if executive management selects a physicist to head the committee, an appropriate level of authority should be delegated to, and support should be demonstrated for, the RSC head. This is particularly true since one or more members of the RSC may be authorized users who supervise the physicist's work in the radiation oncology department. Regulatory agencies have observed that medical physicists have significant time-consuming responsibilities planning therapy treatment. It then becomes important to assess whether the medical physicist will have sufficient time to devote to the RSC as chairperson.

Occasionally, the chair position will be filled by the executive management representative. The advantage of this choice is that executive management, which has ultimate responsibility for the program, would be actively involved in managing the program and would have a broader working knowledge of the program. The disadvantage of having executive management head the committee is that decisions could be made on the basis of incomplete information or financial implications alone, which adversely impact the radiation safety program.

2.3.2 Selecting Other RSC Members

When establishing a new program, the RSO and the RSC chairperson should work together to appoint other people who are interested in serving

on the RSC. The RSO should ensure that all RSC members, to be effective in their role, are adequately trained or possess an appropriate level of knowledge of radiation safety issues and the medical uses utilized at the licensed facility. NRC membership requirements for the RSC for limited scope licensees are described in 10 CFR Part 35, and guidance for broad scope licensees appears in NRC Regulatory Guide 10.5, "Applications for Type A Licensees of Broad Scope." (Note that regulatory guides contain guidance, not requirements.) NRC regulations require that the RSC for a limited specific medical license, should include, at minimum, a representative from each authorized area of medical use, the RSO, executive management, and a nursing representative. NRC regulations also stipulate that the management representative cannot be the authorized user or RSO. User group representatives, such as radiation therapy (oncology), nuclear medicine, radiology, cardiology, research, and pathology, should also be active members. Additionally, NRC regulations require that a quorum be present for each meeting of at least one-half of the RSC membership, including the RSO and executive management.

Typically, the nursing representative on the RSC is a nurse with administrative authority and responsibility to ensure that facility nurses who care for patients undergoing therapy procedures receive required radiation safety training and are aware of relevant radiation safety issues that may affect them or the patients under their care. This individual should have, or should be provided with, a general knowledge of the institution's radiation and radioactive material uses for patient procedures (e.g., diagnostic, radiopharmaceutical therapy, teletherapy, and brachytherapy uses, especially where patients are required to be confined). The RSO, with the assistance of the nursing representative, should develop a mechanism to ensure that radiation safety training, relative to nursing responsibilities, is provided to *all* nurses who will care for patients undergoing radiation therapy. This includes new and temporary nursing staff. Adequate training is particularly important since serious radiation safety incidents have occurred when improperly trained nursing staff who cared for such patients made errors involving radioactive material. Therefore, the nursing representative should be actively involved in the RSC meetings and should be proactive in obtaining information and asking questions on matters related to radiation and patient nursing care. Because of its continued and close contact with patients, the nursing staff, if properly trained, is often the first to notice a radiation safety problem involving a patient and may also be the first to take the critically important initial emergency measures to reduce unwanted radiation exposure to the patient, the nursing staff, other facility staff, and possibly visitors.

2.4 Scheduling and Conduct of RSC Meetings

NRC requires that RSCs hold regularly scheduled meetings at least quarterly. It may also be necessary for the RSC chairperson to schedule additional meetings to discuss issues that arise and demand early intervention or attention. The RSC can conduct considerable business by telephone or mail. For example, members can receive user applications or reports by mail and be ready to discuss them at an upcoming meeting. Voting is also permissible by telephone when necessary. However, NRC requires that all RSC minutes contain recommended actions and the tally of all ballots; therefore, the RSO may want to consider maintaining a telephone log to document such discussions and results.

The RSO and RSC chairperson should ensure that members receive all necessary documents and information before each meeting so that the exchange of information and deliberations reached during the meeting are well researched. Meetings may be as formal or informal as desired by the chairperson. Certain business items are usually discussed first, followed by authorized user applications, license amendment requests, modifications to the radiation safety or quality management (QM) programs, incidents, dosimetry data, and problems involving personnel, equipment, or facilities. The RSO is expected to provide considerable information at the meetings and to be responsive to questions from RSC members. The RSC depends on the RSO to be extremely knowledgeable about the details of the

licensed program and applicable regulatory requirements. If information is not known at the time of the RSC meeting, the RSO can research the issue and make the information available to members at the earliest opportunity. This could include circulating documents to RSC members for comment and discussion. The key is to follow up quickly and thoroughly on outstanding items so that no detail goes unaddressed. Appendix B contains a sample RSC agenda for a meeting.

2.5 Responsibilities

2.5.1 Review and Approval of Authorized Users, User Permits, and License Amendments

One of the RSC's most important responsibilities is to evaluate the training and experience qualifications of applicants who request authorization to use radioactive material at the licensed facility. Holders of limited specific medical licenses are required to apply for and receive an amendment to the license to authorize new individuals to use radioactive material. The exception to this requirement is for a physician who either possesses board certification, as recognized in 10 CFR Part 35, or is identified as an authorized user on another NRC or agreement state license. In this case, the licensee is required to submit notification to the NRC within a specified period of time. Before making an amendment request, the RSC should review the applicant's training and experience documentation to determine whether NRC's criteria have been met. If the documentation is found acceptable, the licensee should submit an amendment request to the NRC and, upon approval, the authorized user may begin to use licensed material. Broad scope medical use licensees have authority to authorize qualified users of licensed material without NRC review or approval. Rather, the RSC reviews the applicant's training and experience documentation to determine if the applicant meets NRC's criteria. If the applicant is deemed qualified, the licensee imparts the authority to the user and no NRC review and approval is needed at this time. The approval process employed by broad scope licensees is reviewed at the time of inspection.

Regardless of whether the facility has been issued a limited specific or a broad scope license, the RSC members should be made aware of the regulatory training and experience criteria that apply to each type of medical use at their institution to facilitate an efficient review of the application and processing of the user's application. Applications for medical use should be carefully reviewed by all RSC members, not just by the RSO. Approval of users and uses may not always go together. For example, a physician may be authorized to perform clinical procedures but may not possess the necessary qualifications to perform research work (or vice versa). The RSC members should clearly understand the applicant's proposed uses. Research involving human use, investigational radiopharmaceuticals, animal studies, or releases to the environment need to be thoroughly reviewed. Typically, the RSO presents and clarifies the information, and it is sometimes helpful to have the applicant attend the RSC meeting to respond to questions as appropriate.

When new users or new uses are authorized, either by the RSC or the regulatory agency, they should be added to the annual audit program to ensure that these new users or new areas of use are monitored for health and safety issues and regulatory compliance.

2.5.2 Review of Consultant's Reports and Findings

As discussed in Chapters 1 and 7, the institution may engage a consultant to augment the radiation safety program. The consultant could either assist the RSO, serve as the RSO, or perform periodic audits of the program. Licensees may also use service companies to provide personnel dosimetry services, leak testing services, teletherapy calibration services, survey instrument calibrations, audits, and other tasks. The reports and related information submitted by consultants and service companies should be carefully reviewed by the RSC. The RSC should not make a habit of accepting the report with no questions asked. A common error made by licensees is to accept consultants' and service companies' reports and findings without reviewing them to ensure that the services were performed in accordance

with the contractual agreement for those services. In addition, the RSC is responsible for acting on the findings identified in the report. If facility personnel take no action, based on a consultant's report that contains errors or misrepresentations of license commitments or requirements, and those actions lead to violations or other problems, regulatory agencies will typically hold the medical institution responsible and not the consultant. Additionally, regulatory agencies may utilize the consultant's report to assess the licensee's response to the findings identified in the report, and may cite the licensee for possible violations identified in the consultant's report if the licensee took no action in response to the findings in the report. Therefore, it is in the licensee's best interest to review a consultant's reports upon receipt and take appropriate action or seek clarification on the findings.

2.5.3 Required Audits and Program Reviews

The RSC, including executive management, shares responsibility with the RSO for the conduct of certain periodic audits of the radiation safety program. In Chapter 8, the staff discusses the conduct of audits and describes required audits in more detail. However, since the RSC has a significant responsibility for the conduct of required audits, the audits are briefly discussed below.

Quarterly Radiation Exposure Audit

At each RSC meeting, the RSO should summarize personnel dosimetry data gathered since the last RSC meeting and discuss the results of required periodic radiation surveys, any significant radiation incidents (including spills, contamination events, misadministrations, and recordable events) that may have occurred. These audits serve as a periodic benchmark to keep the RSC informed of all radiation exposures and incidents. As discussed in Chapter 3, licensees should continually evaluate the personnel monitoring program to ensure that all individuals are monitored as required and that appropriate methods are used, or that historical radiation dosimetry records indicate that personnel monitoring is no longer required.

Annual Audit

Generally, one of the more important RSC meetings is the one in which the RSC members review the results of the annual audit of the radiation safety program. More significant events, radiation exposure summaries, and overall compliance status achieved by authorized users should be thoroughly reviewed. Possible trends should be analyzed and suggestions for timely and effective corrective action should be made. The annual review should concentrate on critical self-analysis to ensure that aggressive and timely corrective actions have been taken throughout the year. Problems should be clearly defined and tracked as "open items" until appropriate corrective action has been taken. Additionally, an assessment of the effectiveness of the corrective actions will help the licensee deter or eliminate future problems and violations.

As Low As Reasonably Achievable (ALARA) Audit

10 CFR Parts 20 and 35 require the establishment of an ALARA program and Part 35 requires that the RSC periodically review the program. The ALARA program should be reviewed at each RSC meeting and summarized at the end of every year. The RSC should also review recommendations (e.g., from employees) on ways to maintain individual and collective doses ALARA. In addition, as part of the annual review, a determination should be made regarding whether the radiation safety program needs to be modified to keep exposures ALARA.

Quality Management Program (QMP) Audit

NRC requires its licensees to review the QMP, at least every 12 months, to determine its effectiveness. Licensees should review all misadministrations, all recordable events, and a representative sample of patient administrations. The review should also ensure that the current version of the QM plan clearly reflects all modifications made to the program to increase its effectiveness and meet the objectives of the QM rule. QMP modifications should be submitted to NRC within 30 days of implementation.

2.6 RSC Meeting Minutes

Proper documentation of the RSC meetings is essential to inform executive management,

internal or external auditors, and regulatory inspectors about oversight of the radiation safety program. Minutes of RSC meetings are especially helpful for members who were unable to attend the meeting, or other interested individuals. The RSC minutes should be written by an individual who understands the technical language used and who can comprehensively describe events to others who may not have an in-depth knowledge of radiation safety program information. The technical, narrative, and decision- making aspects of each meeting should be reflected in clear, concise minutes that convey the key meeting elements without being too lengthy. Contrarily, care should be taken to avoid minutes that are too simplistic and that omit details of key discussions and decisions.

The minutes should clearly reflect voting results and significant discussions and opinions expressed by the RSC and others in attendance. The minutes will rarely stand alone and are usually accompanied by several appended documents, such as user applications, audit reports, dosimetry data, and incident reports. NRC requires that the minutes of each RSC meeting include, at a minimum:

- date of the meeting
- names of members present
- names of members absent
- summary of deliberations and discussions
- recommended actions and the numerical results of all ballots
- ALARA program reviews described in 10 CFR 35.20(c)

Meeting minutes should be prepared and distributed in a timely manner to ensure management and RSC members not in attendance will remain updated on radiation safety issues. Minutes should also list outstanding action items and progress toward resolving these issues. Minutes should be carefully reviewed and concurred on by a qualified individual (e.g., the RSO or RSC chairperson), and the RSC should also concur by voting on the minutes at the next meeting. Appendix C contains sample minutes of an RSC meeting.

2.7 Summary

The RSC is an integral part of the management triangle necessary for effective management of the radiation safety program. The RSC depends heavily on the technical expertise of its members and a cooperative and supportive relationship with the RSO and executive management. Together with the RSO, the RSC can help to ensure that the radiation safety program receives an appropriate level of attention and resources from facility management to ensure regulatory compliance and a safe working environment. The RSC also represents various areas of authorized use at the licensed facility and medical and physics expertise that should serve as a resource for executive management and other facility personnel responsible for the safe use of licensed material.

3 ROLE OF THE RADIATION SAFETY OFFICER

3.1 Introduction

The RSO's primary responsibility is to implement the radiation safety program with the assistance and support of the RSC and executive management. Therefore, the RSO should ensure that radiation safety activities are being performed according to approved policies and procedures, and that all regulatory requirements are complied with in the daily operation of the licensed program. In this chapter, the staff outlines the general responsibilities of the RSO at a medical facility and provides guidance on customizing the role of the RSO to conform to the needs of a specific facility. The major areas of discussion are delegation of authority to the RSO, delegation of tasks, high priorities for the RSO, general duties and responsibilities of the RSO, and additional responsibilities at a broad scope program. Two duties of the RSO, the conduct of audits and incident response, are discussed in detail in Chapters 8 and 9, respectively, and only briefly in this chapter. The conduct of audits is addressed in a separate chapter since it is the most frequently used mechanism to assess the success of the program and involves numerous actions and interrelated steps. The duty of incident response is addressed in a separate chapter to provide expanded information to assist the RSO when responding to an event in a prompt and appropriate manner.

Figure 3 Management Triangle (Emphasis on Radiation Safety Officer)

3.2 Priorities

3.2.1 Health and Safety

The highest priority for the RSO is to ensure that day-to-day operations involving radioactive material are conducted according to policies and procedures designed to adequately protect public health and safety and maintain exposures ALARA. To accomplish this, the RSO should have unhampered access to all activities involving radioactive material. In addition, because of the consequences of actions taken by the RSO in response to emergency situations, the RSO should be intimately familiar with the regulations, applicable regulatory guidance, and license commitments. If the RSO discovers an activity involving radioactive material in which health and safety appear to be compromised to an unacceptable level, the RSO should have the authority to terminate the unsafe activity immediately without consulting with executive management or the RSC. However, at the next available opportunity, the RSO should brief executive management and the RSC chairperson about the event and the RSO's immediate response. These responsible parties should determine the root cause of the problem, collectively identify effective corrective actions, and document such deliberations in the minutes of the RSC meeting. It is helpful for RSOs to attend meetings of professional organizations to keep abreast of new technology, proposed regulations, and guidance developed by applicable professional organizations in order to enhance their role in ensuring public health and safety. Therefore, executive management should identify resources for the RSO, and the radiation support staff if indicated, to attend professional meetings and should secure reference material to help them perform well.

3.2.2 Implementing the Radiation Safety Program

The RSO should be delegated the authority and is responsible for establishing, maintaining, and auditing written policies and procedures to implement various aspects of the radiation safety

program. These policies and procedures should be collected in a centralized location, or close to the area of use, so that they can be easily located in response to an incident or at the time of a regulatory compliance inspection. Appendix D contains a list of minimum radiation safety procedures required by NRC. This list should not be considered all inclusive for licensees of broad scope or large limited specific programs. NRC's Regulatory Guide 10.8 (Revision 2), "Guide for the Preparation of Applications for Medical Uses Programs," contains model procedures that applicants or licensees may use to develop and describe their radiation safety program. Agreement States may have similar guidance documents describing their requirements for policies and procedures in radiation safety programs.

3.2.3 Assisting the RSC

The RSO assists the RSC in ensuring that radiation safety issues are addressed in a comprehensive and timely manner, audits are conducted as required, feedback mechanisms are in place to correct deficiencies, and that adequate resources are provided for implementing the radiation safety program or when modifications are needed. The strongest radiation safety programs are those in which the RSO works closely with the RSC chairperson and principal users on a continuing basis, rather than limiting this work to the periodic RSC meetings. The RSC should keep abreast of the status of the program through the RSO to prevent a tremendous void of information in the event that the RSO discontinues services. In some cases, licensees relied so heavily on the RSO to ensure effective oversight of the licensed program that, upon the RSO's departure, executive management and the RSC did not have adequate knowledge of basic regulatory commitments.

Typically, the RSO takes the lead in gaining first-hand knowledge on the specifics of the licensed program including license commitments, applicable regulatory requirements, and radiation safety, to ensure that adequate protection of the public, patients, and workers is maintained. Although executive management has ultimate responsibility, management typically depends heavily on the RSC and the RSO, and the RSC depends heavily on the RSO to provide complete and accurate information on the radiation safety program. Often, even though RSC members may be technically competent, they may not necessarily be well versed in the regulations or in the commitments of the license. The RSO should also assist the RSC in performing the duties described below by providing precise information on the commitments made in the license and applicable regulations. The RSO provides assistance to the RSC on a wide variety of issues that include the following:

- Reviewing and preparing a summary of the occupational radiation dose records of all personnel for RSC review on a quarterly basis to identify changes in trends and reviewing recommendations on ways to maintain individual and collective doses ALARA;
- Reviewing proposed user applications by performing the initial evaluation on all proposed uses and users and by preparing a summary of the RSO's evaluation and recommendation;
- Performing the initial review of all incidents involving radioactive material, such as major spills and overexposures;
- Reviewing a representative sample of patient administrations to identify recordable events and misadministrations;
- Reviewing all recordable events and misadministrations to verify compliance with, and to determine the effectiveness of, the quality management program.

Appendix B contains a sample agendum for an RSC meeting which should be used as a guideline for developing an agenda that reflects a licensee's specific program and areas for discussion at each meeting. In addition to the agenda, depending on the scope of the program, it may be necessary for the RSO to distribute, in advance of the meeting, additional background information on certain items for discussion.

3.3 Communications

The RSO communicates with individuals at all levels while fulfilling the role of auditor and advisor. A portion of the RSO's time should be devoted to providing consultation on health physics matters and regulatory requirements to authorized users and other persons at all levels of responsibility within the organization who may have special needs or concerns. In effect, because of the unique training and experience requirements of the RSO, RSOs should be relied upon to answer or to find the answer to most technical and regulatory questions brought to their attention. In addition, the RSO plays a key role in the conduct of various audits of the radiation safety program described in Chapter 8.

The RSO is responsible for communicating with the regulatory agency as needed to respond to inspection findings and requests for renewal or amendment of the license, or to seek clarification regarding regulatory commitments or other information. Chapter 10, "Interactions With the NRC" provides a broad overview of this subject.

3.4 General Description of Duties, Tasks, and Responsibilities

The general descriptions that follow identify duties and tasks that are common to both limited specific and broad scope medical licensees. However, this list should not be considered all inclusive since licensees may have tasks associated with special authorizations that are not addressed below. In addition, discussion of duties, tasks, and responsibilities unique to broad scope RSOs are addressed later in this chapter.

3.4.1 Training Program

NRC regulations require that licensees instruct supervised individuals in licensed activities in the principles of radiation safety appropriate to that individual's use of radioactive material, and in the licensee's quality management program (QMP), as required. Regulatory agency inspectors and some licensees often find that the root cause of an incident or misadministration is ineffective training or a lack of training. The RSO should dedicate adequate time to ensure that job-specific training and annual retraining is provided to all authorized users, physicians under the supervision of authorized users, and supervised individuals including technologists, physicists, nursing personnel, and ancillary personnel. The RSO might consider developing a brochure or other training material for employees to consolidate relevant radiation safety information. Some RSOs have found it helpful to circulate a bulletin, newsletter, or notice to inform personnel about new policies, procedures, regulations, or other information relative to their ares of use and responsibility. The RSO, with the assistance of the nursing representative, should develop a mechanism to ensure that radiation safety training, relative to their duties, is provided to all nursing staff who will care for patients undergoing radionuclide therapy. This includes new and temporary nurse employees, if such employees will be required to care for this group of patients. Adequate training for nurses is particularly important since serious radiation safety incidents have occurred when poorly trained nursing staff handle radioactive material improperly. Therefore, the nursing representative to the RSC should be actively involved in the RSC meetings and should be proactive in obtaining information and asking questions on matters related to radiation and patient nursing care. Because nurses have such continued and close contact with patients, the nursing staff, if properly trained, is often the first to notice a radiation safety problem involving a patient in its care and also the first to take the critically important initial emergency measures to reduce unwanted radiation exposure to the patient, nursing and other facility staff, and possibly visitors.

In addition, individuals who work under the supervision of authorized users, including physicians, should receive training on the importance of following instructions provided by the user, written radiation safety procedures, including the QMP, and adhering to all applicable requirements. Authorized users who supervise individuals also have the responsibility to periodically review the individual's use of licensed material and the records maintained to document this use. Appendix E contains sample training

program agenda for several groups of licensee personnel.

3.4.2 Personnel Monitoring Program

In most medical programs, personnel monitoring is required, although the criteria will vary for determining who is monitored, the frequency for exchange of monitoring devices, and the type of monitoring device. Licensees should review applicable regulations, the license application, and licensed activities to determine which categories of individuals should be monitored at any given time. As a result, the categories of personnel or individuals monitored could periodically change, depending on the types and quantities of licensed material in use, review of radiation exposure histories and exposure potential, and revised regulatory requirements. For example, as revised, 10 CFR Part 20 requires licensees to monitor both internal and external doses of individual workers and demonstrate compliance by summing internal and external doses. Personnel monitoring programs may also require that bioassays be performed on workers, depending upon the types, quantities, and use of licensed material, including where and how it is stored, handled, and administered to patients. In addition, declared pregnant occupational workers have different monitoring thresholds from other occupational workers. The RSO should calculate the worker dose from noble gases, evaluate effluent releases because of the potential exposure to the public, and calculate the spilled gas clearance time to ensure that the laboratory or patient procedure room is sufficiently free of the spilled noble gas before any personnel reenter the area.

As part of the licensee's ALARA program, the RSO should establish, with the assistance of the RSC, levels of occupational radiation exposure which, if received, will trigger an investigation. The RSC and RSO are responsible for periodically auditing the personnel monitoring program to ascertain that all persons who should be monitored are being monitored, that badges are returned promptly for processing, and that trends of radiation exposure that may indicate a health and safety problem and radiation exposures exceeding ALARA investigational levels are investigated promptly. The frequency of these audits depends on license conditions and the frequency with which personnel monitoring reports are received by the facility. It may also depend on the number of dosimeter devices. For large broad scope programs, personnel dosimetry may number in the thousands per month and just handling the devices administratively can require considerable resources. However, for most licensees, personnel monitoring audits are usually performed on a monthly or quarterly basis.

3.4.3 Facilities and Equipment

Ideally, the RSO should be involved in the early planning stages of designing new or remodeling existing facilities that will be used for patient procedures involving licensed material, and areas for possession, use, or storage of radioactive material. The RSO should evaluate the hazard associated with the use of licensed material to ensure that the facilities will have adequate shielding available and to ensure the use of any safety equipment that may be required, such as fume hoods, leaded blocks or glass, or fixed radiation area monitors. The use of such noble gases as xenon-133 presents an external source of exposure and requires that the laboratory is at negative pressure compared to the adjoining rooms. Since some licensees use volatile forms of radioiodine, special equipment such as fume hoods and containers may be required. In other cases of radionuclide use, specialized facilities, equipment, and procedures may be needed, including phosphorus-32 plexiglass shielding, brachytherapy treatment room shielding, experimental animal handling and care facilities, and waste storage, packaging, and disposal areas.

The RSO and the radiation safety staff use a variety of specialized instruments to monitor the presence of radioactive material in use. Portable survey instruments are essential, and should accurately measure (1) external radiation fields and (2) surface contamination emitted by various beta and gamma radiation energies from materials in use or storage. These instruments should be available in sufficient numbers for use by all who have survey responsibilities on the RSO's staff and in the individual research and clinical use areas. The instrument used should be correct for the

type and energy of radiation being monitored. For example, a scintillation probe designed to detect low energy gamma radiation would be unsuitable for measuring low energy beta radiation originating from tritium or carbon-14; and a thin-window Geiger- Mueller "pancake" probe would not be suitable for measuring shielding effectiveness around a teletherapy unit.

The finest radiation detection or measurement instruments will be unreliable unless they are properly calibrated for the radiation present. Calibration sources with identical or similar radiation characteristics to the radionuclide intended for measurement should be used during the calibration process. Improper or out-of-date calibrations may lead to misleading survey results, which could result in either overreacting or under-reacting to radiation exposures and contamination.

3.4.4 Incident Response

The RSO is responsible for initiating investigations into possible overexposures from, accidents with, and spills, losses, or thefts of radioactive material. In addition, the RSO is responsible for initiating investigations of deviations from approved radiation safety practice such as unauthorized receipts, uses, transfers, and disposal, as well as misadministrations and recordable events. If the cause of the accident or extent of the spill is not immediately known, it may be necessary to terminate certain activities or to close entire laboratory areas temporarily. If too much emphasis is placed on immediate cleanup of contaminated areas instead of concentrating on gathering information on the extent and cause of the contamination, valuable time may be lost in identifying possible offsite contamination that could result in unacceptable risks to public health and safety. Any of these events may trigger regulatory reporting requirements and the RSO should have a thorough understanding of these reporting requirements in order to avoid more serious enforcement action by the regulatory authority. Some reporting requirements require immediate notification or notification within 24 hours of the incident. Chapter 9 contains a thorough discussion on incident response, and Appendix F describes NRC notification and reporting requirements.

3.4.5 Security of Licensed Material

Although discussed briefly above, NRC considers the security of licensed material to be an important responsibility of the RSO. Licensed material should always be securely stored, transported, or under constant surveillance. Regulatory inspectors often observe, during routine inspections, that laboratories or storage areas containing licensed material are left unlocked, unsecured, or unattended. This creates an unnecessary potential hazard to public health and safety; the potential hazard can be easily avoided by following relatively simple measures. In developing measures to prevent such loss of control, the RSO should work with facility personnel who directly handle licensed material to identify and implement procedures that are effective and not burdensome on the responsible individuals.

On occasion, a shipment of radioactive material may be received before or after working hours. All licensees should implement procedures to ensure that personnel responsible for receiving such packages, such as security guards, receive proper training on the receipt and transport of such packages. Adequate training should include, but is not limited to, procedures for inspecting the outer package upon receipt for damage and leakage; verifying correct facility address; transporting the package to a secured radioactive material storage area; documenting its arrival, and in some cases, notifying a previously identified individual, such as the RSO or a member of the radiation safety staff.

3.4.6 Required Radiation Surveys

In order to ensure the safe use of licensed material, all licensees are required to perform radiation surveys. The RSO is responsible for conducting required radiation surveys, or ensuring that they are conducted, in accordance with license commitments and regulatory requirements. Therefore, the RSO should continually evaluate the radiation safety program and keep current with applicable regulations to determine (1) that all required surveys are being

performed and (2) if additional surveys are warranted. Most regulations for radiation surveys require that survey results be documented in a record which should be maintained for a required length of time. NRC Regulatory Guide 10.8 contains model procedures for the conduct of surveys and sample recordkeeping forms to document the survey results. Licensees may use any recordkeeping format to meet their individual needs, provided that the required information is included.

3.4.7 Radioactive Material Inventory Records

Regulatory agencies require each licensee to retain records of receipt, transferral, and disposal of all radioactive material used at medical facilities. The RSO should establish and maintain an inventory system for ordering, receiving, and properly disposing of radioactive material. Ideally, the inventory system should provide a continual tally of radioactive material possessed by the licensee to ensure and document that regulatory possession limits are not exceeded. Today, there is software available to assist in radioactive material inventory which may be of great benefit to some programs, particularly, large broad scope programs.

The RSO should develop an accounting system that suits the type of licensed program. For example, a small medical facility will generally need to maintain receipt records, disposal records, and records of any transfers to other such licensed facilities as nuclear pharmacies. On the other hand, a broad scope medical licensee will need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the amount used and disposed of, the amount transferred to other laboratories operating under the license, and the amount remaining after decay. The accounting system should also consider radioactive material held for decay-in-storage, near-term disposal, or transfers to other licensees. Routine physical audits by the RSO or staff should test the accounting system to ensure that it is accurate.

3.4.8 Radioactive Waste Management

The RSO is responsible for the supervision and coordination of the radioactive waste disposal program. Medical programs, not involving the use of radioactive materials in research-related activities and not administering iodine-131, will generally not find waste disposal a serious problem. However, those licensees who are involved in research using long-lived radioactive materials and those who administer iodine-131 will need to dedicate space for storing radioactive waste generated by these activities. In some States where access has been denied to the low-level waste sites, licensees may need to provide for long-term interim storage. This will necessitate the RSO and RSC making recommendations to executive management that dedicated space be established for this purpose and submitted to the regulatory agency for approval. Such waste-reduction methods as compaction and incineration, if approved by the regulatory agency, may reduce space requirements. Regulatory agencies may allow licensees to dispose of radioactive waste containing short-lived materials (e.g., half-lives of less than 65 days) provided that certain precautionary measures are taken and records are maintained. This requires that the licensee hold the waste for a minimum of 10 half-lives to allow for an adequate level of radioactive decay. After decay, the licensee should monitor the radiation level of waste before disposal and meet specific disposal and recordkeeping requirements. Licensees are reminded to review the license document since many regulatory agencies list a specific license condition to describe authorized waste disposal methods at the facility.

3.4.9 Records and Reports

Regulations and license commitments require that licensees maintain records and reports to document certain activities of the radiation safety program for minimum periods of time. These records should be accessible to all responsible personnel and regulatory agency inspectors, and should be complete, legible, and maintained up to date in an auditable form. The licensee might consider maintaining duplicate copies of required policies and procedures in separate locations in

the facility in the event of a fire or flood, or other loss. Regulatory agencies recognize the trend for licensees to maintain records in electronic form, and it is acceptable for some records as long as they are easily retrievable and are available during the time of inspection. Therefore, licensees should ensure that, in the absence of the individual responsible for maintaining the electronic records, other individuals know how to retrieve requested records. Note that regulatory agencies may have specific requirements concerning quality assurance and, in fact, may not allow electronic storage of some records, such as those that require signatures. The licensee should be certain to check for restrictions with the appropriate regulatory agency. Appendix G contains a list of NRC notification and reporting requirements.

3.4.10 Certain Medical Devices

In those medical institutions in which other modalities, such as teletherapy, high-dose-rate and low-dose-rate remote afterloaders for brachytherapy, and gamma stereotactic radiosurgery, are used, the RSO will need to be generally familiar with the operation, various safety features, and potential hazards of each modality. All of the equipment used will have primary and ancillary safety devices, such as area monitors, alarms, and status indicators, which will require periodic checking according to instrument manufacturers' operations manuals and license commitments. The RSO should develop procedures for periodically evaluating the performance of these devices in accordance with the manufacturers' guides, regulations, and license commitments.

NRC regulations require the mobile nuclear medicine service licensee to conform to additional technical requirements. Therefore, the person named as RSO on a mobile nuclear medicine license should know about applicable transportation regulations, security requirements, special survey meter and dose calibrator requirements, and tests, as well as about recordkeeping requirements.

3.5 Delegation of Tasks

The responsibilities of the RSO, as designated in the regulations and the license, may not be transferred to other individuals without a clear statement in the license permitting such transfer and approval by the NRC. Many tasks and duties associated with management of the radiation safety program may be assigned or delegated to other qualified individuals; however, the responsibility for ensuring that these tasks and duties are performed correctly lies with the RSO and, ultimately, with the RSC and executive management. For example, the RSO should attend all RSC meetings; no substitute is allowed unless authorized by the regulatory agency. In large radiation safety programs, the delegation of radiation safety tasks becomes a necessity in order to fully implement and oversee all aspects of the radiation safety program. Large broad scope medical programs may have several health physicists who hold degrees in radiological health, physics, or a physical science, or equally trained individuals, who assist the RSO in addressing the technical aspects of the program. Trained technologists working under the direction of the RSO may be used for more routine portions of the program such as laboratory surveys, waste handling, and recordkeeping. Although the task can be delegated to other qualified individuals, the responsibility always remains with the RSO.

Often, inspectors and license reviewers are questioned about who can perform the duties of the RSO while the RSO is away. As discussed in Chapter 2, regulatory agencies expect that, from time to time, a qualified individual will need to fill the role of the RSO during short-term absences for illness, vacation, or work away from the facility. However, this privilege should not be extended indefinitely or on a long-term basis. The RSO's duties and tasks may be delegated to a qualified individual, but the responsibilities of the RSO, and the authority granted by management to the RSO, may not be shared with anyone else. Typically, the NRC does not recognize the position of assistant or alternate RSO because sharing the responsibility with someone else can dilute the RSO's authority and can lead to potential problems in managing the radiation safety

program, particularly when the other individual involved is not given clear instruction or guidance on those aspects of the program that he/she oversees. However, some Agreement States do endorse this management approach and will authorize an alternate RSO on the license. Some qualified individuals who serve as "substitute" RSOs are a health or medical physicist, a nuclear pharmacist, an authorized user, or a chief technologist in nuclear medicine or radiation therapy. The scope of the licensed program and potential problem areas, the length of time an alternate is needed, the training and experience of the individual considered, and the amount of authority delegated by management to this position will help to determine who might best serve as alternate RSO.

3.6 Additional RSO Responsibilities in a Broad Scope Program

The RSO of a broad scope medical license is responsible for more complex matters involving multiple uses and users of radioactive materials, and many broad scope programs include research activities, both medical and non-medical. The broad scope license is written to give the licensee the greatest amount of flexibility, so that research and development can proceed with the least amount of external regulatory involvement, provided that the licensee has implemented the radiation safety program as described in the license application and subsequent amendments. Specific guidance for applications for broad scope medical licenses is given in Regulatory Guide 10.5, "Applications for Licenses of Broad Scope."

Most broad scope licenses permit use of any radionuclide with atomic numbers 1 or 3 through 83, in any form, some of which may require special handling techniques not normally required in a limited specific medical program. Often, RSOs at broad scope facilities have to monitor and maintain special systems and shielding associated with the use, storage, and disposal of radioactive material. Because of the types and quantities of certain radioactive material used in research laboratories, the RSO may need to evaluate, select, design, and supervise maintenance of process control and confinement systems, such as glove boxes and hoods. In some cases, the RSO may become involved in the evaluation, selection, maintenance, and use of respiratory protective equipment. Shielding evaluations, including the determination of the type and amount of shielding needed, are very important because of the types of radiation frequently used.

Additional broad scope matters that require RSO assistance to the RSC include advice and consultation on special incident reporting requirements not normally encountered in a limited specific medical program, development and maintenance of an emergency plan for responding to release of radioactive materials, the determination of need for financial assurance for decommissioning, and development and maintenance of a decommissioning funding plan. These apply to unsealed as well as to sealed sources of radiation. Since broad scope medical licensees transfer radioactive material to other licensed facilities in research-related activities, the RSO should have a comprehensive knowledge of transportation regulations as they apply to materials shipped. Specific information about the transportation of radioactive materials can be found in NRC Information Notice 90-35 entitled, "Transportation of Type A Quantities of Non-fissile Radioactive Materials;" however, this notice should be reviewed with the understanding that changes to the Department of Transportation regulations (49 CFR) and corresponding 10 CFR Part 71 changes were recently completed.

Many broad scope programs include multiple-use locations and unique operations that impact staffing and resource requirements of the radiation safety office. The needs of broad scope programs are constantly changing, so it is important that the RSO furnish the RSC and executive management with current staffing and resource needs. With a constantly changing program, the need to train facility staff in radiation protection becomes crucial. Appendix E outlines a sample program for training medical licensees; it should be used as a guide.

Applicable regulations require that some broad scope licensees establish procedures to ensure completion of safety evaluations of proposed uses

of radioactive material that consider such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures. In a medical broad scope program, the RSC, with the assistance of the RSO, uses the established procedures to review and approve authorized users, uses, and facilities as authorized by its license. The RSO often serves as a facilitator by advising the RSC on matters related to the approval of proposed authorized users.

NRC's training and experience criteria for approving medical/human use is detailed in 10 CFR Part 35, Subpart J. However, the training and experience criteria for proposed non-medical use by researchers should be developed by the RSO and RSC. A classification scheme to define minimum criteria can be developed on the basis of radiotoxicity and levels of activities used. The same scientific basis can be useful for establishing standards of design for laboratories, required equipment, personnel monitoring, and survey requirements.

In addition to the tasks and responsibilities described above, the RSO for a broad scope medical license should assist the RSC with such matters as determining compliance with other regulatory authorities. Other agencies may include the Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Department of Energy (DOE), local ordinances, specific license conditions, and conditions of materials use specified by the RSC.

A broad scope medical program may be authorized to approve and conduct research involving the use of radioactive drugs or radiation-emitting devices in humans. Such research may, however, require prior FDA approval. In addition, final approval to conduct research studies involving radiation typically requires that the broad scope licensee contact an Institutional Review Board (IRB), a Radioactive Drug Research Committee (RDRC), or other appropriate committees that review and accept research studies based on patient and human research subjects safety, ethical considerations, and scientific merit. The RSO should be involved in the approval process to serve as a central institutional authority through which all applications for the human use of radioactive materials are submitted so as to ensure that the radiation safety (research subject and occupational worker) and regulatory aspects of the study are appropriately addressed.

The RDRC is an institutional committee defined under FDA regulations (21 CFR Part 361) that can approve research studies intended to obtain basic information regarding the metabolis (including kinetics, distribution, and localization) of a radioactively labeled drug, or regarding human physiology, pathology, or biochemistry. RDRC approval authority does not, however, extend to research involving the use of radioactive drugs for immediate diagnostic studies or therapeutic purposes (i.e., to carry out a clinical trial). The IRB is an institutional committee, mandated by the Department of Health and Human Services, which reviews all research studies (radioactive and nonradioactive) performed within the institution or by investigators affiliated with the institution. The principal objectives of the IRB are to ensure that the potential benefits to be gained from the research study exceed the associated risks to the subject and that the research subject is fully informed of the study procedures, potential risks and benefits, and a person's rights as a research subject.

3.7 Summary

In summary, as the focal point of any radiation safety program, the RSO may have a broad spectrum of responsibilities. The RSO's primary responsibilities are to ensure adequate protection of public health and safety, and that day-to-day operations are conducted in accordance with approved procedures and in compliance with regulatory requirements. In addition, it is typically the RSO who responds first to incidents involving licensed material and conducts required program audits. Each licensed program should be considered unique in both the scope of licensed activities and its organization. Therefore, each licensee should evaluate its own radiation safety program to determine the role of the RSO, and whether additional trained radiation safety staff

are needed to support the RSO. Each licensee should also establish a mechanism to ensure adequate involvement in the program by the RSC and executive management. Additionally, when determining how large a role the RSO will play in any licensed program, management should consider that many RSOs with clinical responsibilities are also responsible for the safe use of licensed material in such departments as radiology, nuclear medicine, and radiation therapy or in a clinical laboratory, and therefore, need adequate time to devote to the role. Although the RSO is the primary individual responsible for day-to-day operations, executive management is ultimately responsible for the program and should ensure that adequate resources are provided to the radiation safety program, including the availability of the RSO.

4 SELECTING A RADIATION SAFETY OFFICER

4.1 Introduction

The RSO is a critical component of the management triangle because the RSO, with the assistance of the RSC, is responsible for implementing and maintaining the licensed radiation safety program. Executive management is obligated to select an RSO who has sufficient training and experience to address all facets of the radiation safety program. However, compliance with the training and experience criteria described in the regulations, whether they are NRC or State criteria, may not be sufficient qualifications for the individual to be effective. For example, the RSO candidate should also possess good management skills, welcome the responsibility, and be willing to dedicate enough time to ensure that the required tasks to implement or maintain the radiation safety program are properly performed. The careful selection of the RSO is a crucial task for executive management. Therefore, to assist licensees in this selection process, this chapter discusses *minimum* RSO qualifications for different types of licenses, as well as the advantages and disadvantages of certain categories of RSO candidates, and makes suggestions for locating qualified candidates.

4.2 Qualifications

To implement the radiation safety program, the RSO is responsible for overseeing the day-to-day operations and should have unhampered access to all levels of the organization. Executive management should empower the RSO to terminate an unsafe activity immediately without being challenged and, in some cases, without prior coordination with the RSC or executive management. Therefore, executive management should select an individual in whom it has confidence to delegate this authority.

The nature of activities conducted under a limited specific versus broad scope license can be extremely different. The magnitude of potential safety-related problems requires the RSO of a broad scope license to be more knowledgeable in various aspects of health physics. Because NRC criteria for acceptable training and experience for the RSO of the two types of licensees are different, in the next two sections the staff discusses *minimum* NRC training and experience criteria for each category of licensee.

4.2.1 Limited Specific Licensee

The limited specific licensee usually performs routine diagnostic or therapeutic procedures or both with Food and Drug Administration (FDA)-approved radiopharmaceuticals and sealed sources. NRC's training and experience criteria for qualifying an RSO for a limited specific program are described in 10 CFR Part 35, Subpart J, and allow three training pathways: certification by professional boards recognized in the regulations, specific classroom training, and work and clinical experience. Being listed as an authorized user on the license is also acceptable. Additionally, individuals may qualify if they have been previously authorized as RSOs at a facility of similar size and scope. NRC requires that the training and experience be obtained within seven years preceding the date of the application, or that the applicant should have had related continuing education and experience since completing the required training. NRC's training and experience requirements for limited specific licensees are outlined in Appendix H. (Agreement State regulations have different requirements.)

Some professional boards are recognized in NRC regulations because, as part of the certification criteria, applicants have successfully completed a radiation safety component determined by NRC to be adequate. An alternate pathway consists, at a minimum, of basic classroom and laboratory training in courses related to radiation safety and direct work experience under the supervision of an RSO in a medical facility of similar or larger size and similar or broader scope. Typically, classroom and laboratory training comprises course work in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiopharmaceutical chemistry. Although appropriate classroom and laboratory training is

an important benchmark for demonstrating adequate qualifications, the practical experience gained while working under the supervision of an RSO in a medical facility cannot be overstated. It is through this practical experience that an individual learns to apply the technical knowledge gained from classroom and laboratory training. NRC regulations require a minimum of 1 year of practical experience.

4.2.2 Broad Scope Licensee

Broad scope medical licensees are authorized to use a variety of radiopharmaceuticals and sealed sources for diagnostic and therapeutic patient procedures and other human use, and for both medical and nonmedical research. Because of the nature of this varied program, broad scope licensees generally need more flexibility in managing their programs than do limited specific licensees. For example, the RSC, with the assistance of the RSO, typically approves facilities, equipment, uses, and users. For this reason, broad scope licensees should have staff including the RSC, and particularly the RSO, who are eminently qualified to review and approve these requests.

Generally, an RSO at a broad scope facility should have experience using and supervising a broad spectrum of isotopes, activities, and uses. Although this RSO is not required to have direct experience with *all* isotopes used in the broad scope facility, the RSO should know when to ask for assistance from individuals who have the appropriate expertise. Applicants for the RSO position should also have practical experience in certain tasks before being considered acceptable candidates for the position. An RSO in a broad scope facility should have experience in such areas as laboratory auditing, personnel monitoring, bioassay, contamination control, investigation of incidents, training personnel, instrumentation and calibration, material inventory and accountability, radioactive waste disposal, transportation, and the use of an RDRC and an IRB. See Section 3.6 for further discussion on RDRCs and IRBs.

Also desirable in a candidate are such management abilities as developing and administering a budget, supervising a staff, being familiar with human resource matters, and having good writing and oral communication skills. A thorough knowledge of regulatory requirements is essential to maintaining compliance for an RSO of any type of licensed program; however, this knowledge becomes critical for the more complicated program of a broad scope license.

Appendix I provides guidance on the type and length of formal education, certification, and experience that NRC staff recommends for RSOs of broad scope programs. This guidance is based on similar guidance described in NRC Draft Regulatory Guide OP 722-4, "Qualifications for the Radiation Safety Officer in a Large-Scale Non-Fuel-Cycle Radionuclide Program." The guidance in Appendix I can be used to determine if a candidate has sufficient practical or applied health physics experience based on education or certification. The higher the degree of formal education in health physics or radiological health, the less applied health physics experience is required. Regardless of education, however, the licensee should thoroughly review each candidate's experience. Licensees of broad scope programs should ask each potential candidate to disclose complete information about previous training and experience.

Appendix J contains a checklist that licensees of broad scope facilities can use to analyze an RSO applicant's training and experience. However, this checklist should not be considered all inclusive. Licensees are encouraged to develop criteria that address the unique needs of their facilities. The checklist is simply a tool that can be used to identify acceptable RSO candidates easily. The checklist may also be useful for preparing and submitting documentation of credentials to regulatory agencies for a candidate whom the licensee believes is qualified to act as RSO.

After establishing appropriate criteria for evaluating candidates, holders of broad scope licenses should establish and define a process to review the training and experience of each applicant. The selection process can be time intensive; therefore, if the RSC has been established, it may consider setting up a subcommittee to review the credentials of all

applicants and to prepare a preferred candidates list. The credentials of these selected candidates can then be carefully reviewed by the entire membership of the RSC. The RSC can rate the candidates and recommend the most qualified individual to executive management. Several other methods have also proved to be equally effective, but the actual selection process is left to the discretion of executive management. Although the licensee is obligated to select the RSC's candidate, the final approval of an RSO for a facility is the authority and responsibility of the regulatory agency.

4.3 Interpersonal Skills

In addition to finding an individual who is technically competent, not unlike any other personnel selection, the licensee should attempt to find one who works well with other people. After all, an RSO depends on other individuals to follow procedures and complete tasks, and should interact with them as needed to ensure an effective radiation safety program. An RSO's effectiveness in managing the program is often dependent on the ability to convey important regulatory and technical information from one group to another, and the rapport established with members of the organization.

The RSO should convey information to all levels of the organization, from the executive management of the facility to the laboratory staff. Additionally, the RSO should convey licensee policy and regulatory requirements for the use of radioactive material to primary users and laboratory staff; should work with the RSC to identify failures or weaknesses in the radiation safety program; should recommend corrective actions to avoid health and safety problems and noncompliance; and should counsel executive management so it can make informed decisions regarding appropriate disciplinary actions for infractions against a licensee's policy or violation of regulatory requirements. Also, from time to time, it will be necessary for the RSO to convey licensing requests and inspection responses to regulatory agencies. Therefore, it is imperative that the RSO's communication skills, written and verbal, be effective.

Good interpersonal skills are important to facilitate management of the radiation safety program. Problems can occur when technically qualified RSOs become ineffective because they become involved with personality conflicts or power struggles within the organization. The RSO cannot perform all the tasks required for implementing the program without the cooperation of other qualified individuals. Therefore, the RSO should be skilled in delegating tasks and negotiating issues with staff on behalf of the institution. The RSO should never hesitate to aggressively pursue issues related to health and safety, and regulatory compliance. In other words, the RSO should be assertive, but diplomatic, and should be willing to participate actively in auditing and, in some cases, supervising the use of radioactive material in the facility by conducting both announced and unannounced audits. The RSO should be "comfortable" with exercising authority when addressing and following up on safety or compliance offenders. For licensees who use consultants to augment their radiation safety programs, the RSO should be knowledgeable of the defined role of the consultant and should work effectively to ensure that all aspects of the license program are audited and that findings are addressed with appropriate followup action.

4.4 Advantages and Disadvantages of Certain Categories of Individuals as RSO

The discussion that follows highlights the advantages and disadvantages observed by regulators when licensees select certain categories of individuals to fill the role of RSO. Generally, the category of individual selected and authorized as RSO is dependent upon the size and scope of the program; any of the individual categories discussed below could ultimately be the best RSO for a particular licensed program.

4.4.1 Health and Medical Physicist

Health and medical physicists represent two categories of professionals that may have varied responsibilities in a medical facility; however, there is usually a distinct difference between the two groups with respect to their roles. For

example, health physicists employed in the medical arena are typically involved with such radiation program issues as radioactive waste processing, personnel dosimetry, equipment quality control and acceptance testing, and radiation monitoring. Medical physicists are typically responsible for treatment planning for brachytherapy, teletherapy, linear accelerators, or gamma stereotactic radiosurgery patient procedures. Both categories of individuals routinely work with and are responsible for the safe use of radiation sources which pose the greatest potential for harm to facility patients and workers. As a result, these individuals possess a great deal of practical knowledge and are adept at emergency response in the event of a radiation incident. Furthermore, their academic or technical training typically prepares them thoroughly for dealing with many of the complex technical issues associated with radiation safety program management.

Unfortunately, on occasion, health or medical physicists, in response to job assignments, may focus almost all of their attention on a single area of the radiation safety program, leaving other areas virtually unattended. For example, the medical physicist–RSO who works in an institution that has an active nuclear medicine program, as well as a therapy program, may become so involved with the therapy program that very little time is devoted to diagnostic nuclear medicine activities. Therefore, if executive management selects a health/medical physicist to serve as RSO and also to function in other capacities, it should ensure that the health/medical physicist–RSO is provided with, and dedicates adequate time to, the program and has an interest in exercising oversight of each area of responsibility. Generally speaking, because of their relevant education and hands-on responsibility with licensed material, health or medical physicists should, in most cases, be considered serious contenders for the position of RSO.

4.4.2 Physician

Physicians are frequently designated as RSOs for limited specific licensed programs because of their direct involvement with licensed material, notable stature and influence in the organization, and the fact that authorized physician users meet NRC's training and experience criteria. Physicians who are interested in the role can be very effective RSOs in some programs. Unfortunately, regulatory agencies have observed many cases in which physicians failed to fulfill the RSO role and discharge RSO duties properly. On several occasions, physician–RSOs have delegated duties to other individuals and failed to follow up on tasks to ensure they were performed as required. Often, physicians are so busy practicing medicine that they do not have sufficient time to fill the role of RSO. In some cases, physicians were simply not interested in performing RSO duties, and only agreed to perform them thinking that the position should be filled by a physician, or that the RSO position provided a professional credential. Some physicians were not accurately informed by executive management of the RSO's responsibilities, and accepted the position with little or no background information. If licensee management selects a physician user as RSO, it should ensure that the physician welcomes the responsibility and understands the obligation and time commitment. It may be necessary to provide the physician–RSO with radiation safety training specific to the licensed program, since each program has different needs, uses, and license commitments. Training may include formal courses offered by professional organizations, universities, or consultant services, and on-the-job training at other licensed medical institutions or facilities of similar size and scope.

Additionally, regulatory agencies recognize that it is no longer common practice for physicians to be employed directly by medical institutions. Instead, most physicians work out of private or group practices under contract to the medical institution; therefore, a physician–RSO's line of authority within the licensed facility could be neither clear

nor strong. Therefore, it may be appropriate in some cases to consider establishing a contractual agreement between the physician–RSO and executive management regarding the licensee's expectations of the physician as RSO.

4.4.3 Technologist

Technologists are usually detail oriented because of their technical training and work experience. They are familiar with the hands-on use of the radioactive material in day-to-day operations as well as with the intricacies of the nuclear medicine or radiation therapy program. However, there are inherent problems associated with designating a qualified nuclear medicine or radiation therapy technologist as RSO. Because the technologist performs many of the tasks that should be monitored by the RSO, there is a potential for conflict of interest. Also, the technologist–RSO should oversee the radiation safety aspects of the use of radioactive material by the physician user who may be the technologist's supervisor. There is a potential for the physician user/supervisor to intimidate or ignore the technologist–RSO. Therefore, if licensee management decides to select a qualified technologist as RSO, it should provide adequate management support and a clear line of authority to the technologist–RSO for that individual to be effective. Additionally, the technologist should welcome this management challenge and work to build a professional reputation among executive management, the RSC, authorized users, radiation workers, and regulatory agencies.

4.4.4 Nuclear Pharmacist

Nuclear pharmacists are adept at handling large quantities of radioactive material and are familiar with FDA requirements. Such knowledge may be very useful in programs that are involved in nuclear medicine procedures and in research and development. Because the nuclear pharmacist's activities generally involve compounding and dispensing radiopharmaceuticals, not actually administering them, nuclear pharmacists may require experience beyond their scope of use. In addition, the pharmacist may lack sufficient experience with sealed sources used for patient therapy. The licensee should review the nuclear pharmacist's practical experience carefully to verify that it is adequate to meet the facility's needs or should give the potential nuclear pharmacist–RSO an opportunity to gain additional classroom and laboratory experience to become qualified as an RSO.

4.4.5 Consultant

Occasionally, when licensees determine that they do not have personnel who are qualified or willing to assume the role of RSO, they contract for an independent health physics consultant to serve as the authorized RSO. Consultants can amass a wealth of information from experiences gained while consulting in a variety of programs. Many consultants offer such contractual services, as leak testing or instrument calibration, which most licensees need and do not have the facilities or expertise to successfully perform. Executive management should be aware that hiring a consultant may mean engaging a firm of consultants. Some consultants are very busy overseeing several licensed programs simultaneously and may not be able to commit adequate time on site to fulfill their contractual commitments. If licensee management plans to select a consultant to perform the duties of RSO, and not just to augment the RSO, it should ensure that the consultant spends enough time on site to implement the program adequately. If the consultant delegates tasks to other individuals working at the facility or within the consultant's own firm, there should be a clear understanding of each person's responsibility.

4.5 Locating Qualified Candidates

Licensees, particularly those in remote areas, often comment that they have difficulty locating qualified candidates. The method of recruitment will vary with the size and scope of the radiation safety program and the candidate qualifications that are needed. In situations in which the licensee wants an RSO who has special qualifications, the licensee may need to hire a personnel recruiter to organize a national search. Using a personnel recruiter will incur a cost and may not be feasible

for smaller limited specific programs. However, several professional organizations, such as the Health Physics Society, the American Association of Physicists in Medicine, and the Society of Nuclear Medicine advertise job opportunities in their publications. Such advertising may also incur a cost, but these societies often hold local and regional chapter meetings that provide free recruitment opportunities for licensees.

Establishing a network of colleague contacts can provide a source of qualified candidates. Organizations such as the American Hospital Radiology Administrators provide opportunities for midlevel management to make contact with their colleagues nationwide. Colleges and universities that offer relevant educational programs can be a source of technical candidates. Some teaching programs offer the appropriate classroom and laboratory training and the work experience necessary to qualify a candidate for the RSO position. The licensee should ask for information about the content of the particular training program to verify that it satisfies the training and experience criteria for an RSO for the size and scope of the licensed program in question.

4.6 Summary

Careful selection of the RSO is crucial to the effective management and implementation of the radiation safety program. There are many qualities or characteristics that executive management should consider when making this selection. One category of individual as RSO at one institution may not be appropriate at another institution of different size and scope. Each facility should address this issue by considering its unique needs and resources. Executive management should seek a person who is technically qualified, who communicates effectively, and who manages people well. The role of RSO should never be forced onto an individual who does not want the responsibility or is not willing to dedicate enough time to performing the required tasks. Executive management should understand the time commitment and should allocate sufficient time to the RSO to complete the required tasks. None of the people in the RSO categories described in this chapter can be expected to perform adequately as an RSO if they are also expected to perform *full-time* clinical, research, or technical duties. Management should also be certain that the candidate understands the obligations and time commitment before he/she accepts the RSO position.

RSO Requirements for Audits, Reviews, Records or Reports

1. Events that occur at random and are emergent in nature, to be reported/documented as they occur			
Nature of Event:	**Discussion**	**Report goes to**	**Reference**
Medical Event	Read the reference to be sure it really is a medical event. May require immediate reporting depending upon severity	NHPP	35.3045 35.3047
Spill	Reporting depends upon magnitude.	RSC, possibly Management, possibly NHPP	
Loss of control of material (this could be as simple as a research package left alone for an hour, a flood source left out overnight, etc)	Depending on amount of material and exposure rate, reported immediately (24 hrs), within 30 days, or file for review at the next inspection and report at next RSC meeting.	Record or NHPP depending upon severity	10 CFR 20.1801, 2201, 2202, 2203
Incident or Concern	E.g. Personnel discover that CT scanners actually produce exposure (although less than ALARA) in control rooms and adjacent areas.	RSC	

2. Events that occur at random, but are non-emergent, report/document as they occur			
Nature of Event:	**Discussion**	**Report goes to**	**Reference**
Evaluation of administration of radiopharmaceuticals requiring a written directive.	Best if review after each procedure. If not, do quarterly. Requirement now to do at each RSC meeting.	RSC	
Inspections-e.g. NRC, NHPP, OIG, JC, OSHA etc	Write up a report of finding. Undoubtedly your Quality Management Dept will require an action plan if there are items the agency would like action on.	RSC, sometimes the agency	
Human subject studies involving radiation	Whenever a protocol is an IRB agenda item, an analysis is required.	IRB	
Evaluation of patients for skin injury from fluoroscopy	Not a requirement per se, but there should be a process for evaluating patients for potential skin injuries when exceeding certain amounts of fluoroscopy (time or dose based)	RSC, patient safety officer	
Close-out Surveys	Labs not using radioactive material for over 24 months are to have a close out survey. Now RSC standing agenda item	Decommissioning record, RSC	
Waste disposed by decay in storage	The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.	RSO files	§ 35.2092
Waste Shipped for Transfer or Burial		record	§ 20.2006

3. Events to be reported/documented quarterly (note for RSCs that meet semi-annual, the report is semiannual)			
Nature of Event:	**Discussion**	**Report goes to**	**Reference**
Review of Dosimetry/ALARA compliance	RSOs should have a contract that alerts them whenever ALARA values are exceeded. Now an NHPP requirement.	RSC	
Security	New NHPP requirement to review security at each RSC meeting. Includes cooperation with Police, two delay method reviews, transfer or disposal of disused sources.	RSC	
Evaluation of administration of radiopharmaceuticals requiring a written directive.	Best if review after each procedure. If not, do quarterly. Requirement now to do at each RSC meeting.	RSC	
Status of footprint management	Now required as standing agenda item at RSC meetings.	RSC	
RSC Tracking Matrix	Now by NHPP as part of a standardized format for RSC minutes	RSC	
RSC minutes	New NHPP requirement to submit to RSC's oversight committee in 30 days, have Director's signature in 45 days.	RSC, oversight committee, Director	
Nuclear Medicine QC Review	Good practice to review quarterly. Include review of Dose Calibrator checks, receipt and inventory, surveys, and bioassays.	RSC	
Surveys	Good practice to review quarterly, including research.	RSC	
Sealed Source Inventory	VA requirement for quarterly, NRC requires test for leakage semi annually	record	

4. Events to be reported/documented semi-annually			
Nature of Event:	**Discussion**	**Report goes to**	**Reference**
Airflow rates (required for those who use radioactive gasses)	FMS should have it on their PM schedule	record	
Radioisotope Research Lab Audit Review	RSO is a member Research Safety Subcommittee which is required to review labs semi-annually.	record,	
Sealed source test for removable contamination	Not to exceed six month intervals	record	35.3067

5. Events to be reported/documented annually			
Nature of Event:	**Discussion**	**Report goes to**	**Reference**
RSO Program Review- to include security review, footprint management status review	Needs to include specified items. In my opinion, NHPP will specify a format in the future	RSC	
NESHAPS (annual), based on material received-need research pkg log and Nuc receipt, esp NaI-131 and other therapies		record	
Sewer release calculation-need sink log totals for the year.	Assess compliance with limits.	record	
Management Briefing	NHPP, in my experience, has not required a formal meeting. However, if you can, you should do it for several reasons.	Record, perhaps RSC.	
Inventory and testing of radiation protection equipment (i.e. lead apron check)	Often (but not always) a big Joint Commission issue despite journal articles that argue that for a significant exposure, you would be well aware of the "hole".	record	
Testing of X-ray machines by a qualified Medical Physicist			Some VA document
Annual exposure report to personnel	Individuals for whom monitoring is required because they are likely to receive in excess of 10% of the allowable limit.	individual	20.1502
Exposure to the public	Evaluate if exceeds 100 mrem-locations of concern would be waste storage, hot labs,		§ 20.1302, § 20.2107

Radiation Safety Committee Sign-in Sheet

May 27, 2010 @ 1:00 PM

Representing Service	Member Name/Title	Signature
Chair Member from Radiology Service (physician)	**Cheryl Baker, M.D.** Service Chief	
Radiation Safety Officer	**Michael T. Hackett, MS** Radiation Safety Officer	
Member from Management	**Keith Neeley** Acting Associate Director For: **Donna Jacobs, FACHE** Acting Director	
Member from Nuclear Medicine Service (physician)	**Wei-Jen Shih, M.D.** Service Chief, Clinical Authorized User	
Member from Nuclear Medicine Service (technical staff)	**Vickie Kiefer, CNMT** Chief Technologist	
Member from Patient Care Services (Nursing)	**Shannon Hardin, R.N.** Nurse Manager for 2-South/ Cardiac Cath	
Member from Research Service	**Steve Brown, Ph.D.** Research Chemist, Research Safety Manager, Research Authorized User	
Member from Radiology Service (technical staff)	**Vacant**	
Member from NAGE	**Jon Jones** NAGE Safety Officer	
RECORDER:		
GUESTS:	**Rebecca Wierzbinski, CNMT** Nuclear Medicine Technologist	

Radiation Safety Committee Attendance & Minutes Tracking for 2010 Reviews

Time period being reviewed at the Radiation Safety Committee (RSC) meeting (i.e., during 2010)		Jan-Mar	Apr-Jun	Jul-Sep	Annual & Oct-Dec	Total # of RSC Meetings	P = Present	R = Represented By	E = Excused	A = Absent	V = Vacant
Scheduled Date of Radiation Safety Committee meeting (i.e., set up for the 4th Thursday of 2nd month of the qtr following the review period except Nov when it is the 3rd Thursday)		Scheduled for 05/27/10	Scheduled for 08/26/10	Scheduled for 11/18/10	Scheduled for 02/24/11						
Actual Date of Radiation Safety Committee meeting		**05/27/10**									
Scheduled Date above RSC minutes presented to Environment of Care Council (i.e., set up for the 2nd Thursday of 3rd month of the qtr following the above mentioned RSC meeting)		Scheduled for 06/10/10	Scheduled for 09/09/10	Scheduled for 12/09/10	Scheduled for 03/10/11						
Actual Date above RSC minutes presented to Environment of Care Council		**06/10/10**									
# days from RSC meeting to ECC meeting (needs to be within 30 days)		**14**									
Actual Date above RSC minutes reviewed & signed by the Director		**06/14/10**									
# days from RSC meeting to Director's review (needs to be within 45 days)		**18**									
Radiation Safety Committee (RSC) Membership		**RSC Attendance**									
Representing Service	Member Name/Title										
Radiation Safety Officer	**Michael T. Hackett, MS** Radiation Safety Officer	P				1	1	0	0	0	0
Member from Facility Executive Management	**Donna Jacobs, FACHE** Associate Director (AD)	R by W. Keith Neeley, Acting AD				1	0	1	0	0	0
Member from Nuclear Medicine Service (physician, clinical authorized user)	**Wei-Jen Shih, M.D.** Chief of Nuclear Medicine Service, Clinical Authorized User	P				1	1	0	0	0	0
Member from Nuclear Medicine Service (technical staff)	**Vickie Kiefer, CNMT** Chief Nucelar Medicine Technologist	P				1	1	0	0	0	0
Member from Patient Care Services (i.e., Nursing)	**Shannon Hardin, R.N.** Nurse Manager for 2 South/ Cardiac Cath	P				1	1	0	0	0	0
Member from Radiology Service (physician)	**Cheryl D. Baker, M.D.** Chief of Radiology Service, Chair of Radiation Safety Committee	P				1	1	0	0	0	0
Member from Radiology Service (technical staff)	**Vacant**	V				1	0	0	0	0	1
Member from Research Service (research authorized user)	**Steve Brown, Ph.D.** Research Chemist, Research Safety Manager, Research Authorized User	P				1	1	0	0	0	0
NAGE union representative	**Jon Jones** NAGE Safety Officer	A				1	0	0	0	1	0
# of RSC members present (P)		6									
# of RSC members represented by (R)		1									
# of RSC members excused (E)		0									
# of RSC members absent (A)		1									
# of RSC member positions vacant (V)		1									
Total # of RSC members		9									
Was a quorum* present?		Yes									

* Quorum: at least one-half of the committee membership is in attendance and must include the Chair (or designee), Radiation Safety Officer, and a management representative (or designee).