Haverkamp, Trisha

From: Dwyer, James
Sent: Friday, June 19, 2015 11:04 AM
To: Haverkamp, Trisha
Subject: FW: Mon Gen
Attachments: Mon Gen RSCM 12.15.14.pdf; Mon Gen tech education 12.15.14.PDF; Mon Gen WD 2 8 2013.PDF; Mon Gen WD 2 26 2013.PDF; ATT00001.txt

-----Original Message-----
From: Gallaghar, Robert
Sent: Tuesday, June 09, 2015 4:46 AM
To: Dwyer, James
Subject: FW: Mon Gen

Jim,

Here is the email from Monongalia's RSO, Mike Perna.

-----Original Message-----
From: MARK PERNA [mailto:markperna@mac.com]
Sent: Monday, January 05, 2015 5:36 PM
To: Gallaghar, Robert
Cc: Brenda Debastiani; Mike Snyder
Subject: Re: Mon Gen

Bob:

Attached are the redacted written directives you requested. I'd like to update you on our investigation into our oversights and what we've done in response.

A few months prior to the incidents, Mon Gen changed radiology groups. In both the previous radiology group and the one before that going back about 15 years, all of Mon Gen's authorized users were authorized for 35.300 materials. When the techs needed a signature, they could go to any authorized user and get a legitimate signature. In the new radiology group, only about half of the authorized users are authorized for 35.300 materials. The two written directives at issue were only the 4th and 5th done after the radiology groups changed. I believe that that the root cause was simple oversight due to the newness of the changed circumstances.

We took the following actions:

Within an hour of the inspection on December 15, we had John Leon, M.D. review and sign off on the two written directives. Dr. Leon is authorized on our license for 35.300. He found both to be acceptable. This was unsurprising. We have a very standardized I-131 program. With only a couple of exceptions since the inception of our program in 1992, we use discrete prescribed doses of I-131; 10, 15, 20 or 30 mCi for hyperthyroid therapies and 100 mCi for cancer therapies. In this case, the doses were 30 and 100 which are standard doses. All personnel are aware of the standardized doses and this awareness helps to prevent dosing errors. If a dose is not one of the typical prescribed doses, it would be questioned prior to administration. We realize that having the authorized user sign off on the doses more than a year after the administration doesn't make up for not having it done prior to administration however we wanted to verify internally that we hadn't put any patients at risk and we are confident we have not.

Also within an hour of the inspection, we provided training for the nuclear medicine staff on duty that day. The remaining staff received the training on their first day back at work after the inspection. The training reviewed who is authorized to sign written directives for 35.300 procedures. We also have a list of the 35.300 authorized users posted in the hot lab and we intend to update the list as it changes. I've attached the documentation of this training.

I also prepared an amendment on the day of the inspection to add Dr. Kupec, signer of the February 8 written directive, as an authorized user for 35.100, 200 and 300 materials (we added two other physicians at the same time). Due to the holiday, it took until December 30 to get the necessary signatures. It was faxed to the NRC before the end of the work day on December 30.

Dr. Rosiello is already on our license for 35.100 and 200 uses. He has been in practice for so long that his training is no longer current for immediate addition for 35.300 uses. We are evaluating our options. If you have any suggestions, we would be very interested in hearing them.

I would also like to address the radiation safety committee issue.

During our previous NRC inspection, we were told that we needed physician representation on the Committee however we misinterpreted the requirements. While I'm sure the NRC inspector was clear, we didn't understand that the representative was required to be an authorized user of each type of therapy. We also did not refer to the regulation because we believed that we knew the standard. All of that is explanation for our accidental oversight not excuse for it. Even though we fell short of the regulation, we thought we were in compliance and had made a good faith effort to meet the requirement.

For brachytherapy uses, we added the only physician who is involved in the oncology program, Dr. Stewart who is also our 35.400 authorized user. Our I-131 program is overseen by our radiologists. The radiology group at Mon Gen is a group that services multiple hospitals in the area. The group's medical director is Dr. Migaiolo. He is the radiologist most frequently at Mon Gen and is the administrative liaison between the hospital and the rest of the group. Any medical or radiation safety related issues or concerns that any radiologist would have in the group would be communicated through Dr. Migaiolo. Because of his position within the group and his relationship with the hospital, we thought he would be the ideal candidate to represent the radiologists. Unfortunately, he is not authorized for 35.300 procedures.

Our radiation safety committee meets on a quarterly basis to primarily review X-ray use. Our I-131 program is very small (we've only done 21 cases since 2009). Outside of a medical event in brachytherapy this past year which was an anomaly that was driven by odd patient anatomy and didn't result in any harm to the patient, we have had very few issues with brachytherapy and the general nuclear medicine program has not had any significant issues in the 23 years I've been associated with the program. I'm reasonably sure we've never had a nuclear medicine tech exceed ALARA I (500 mrads in a year). We do, however, have a robust cath lab program and there are many radiation safety issues there that require our attention and tend to occupy the bulk of the committee's time.

We took the following actions upon discovering our misunderstanding:

We added John Leon, M.D. to the committee and had an emergency radiation safety committee meeting on December 15 at 2:00 PM. Dr. Leon, Dr. Stewart and myself conferenced into the meeting. I've attached a copy of the meeting minutes.

We have also decided to have a single official radiation safety committee meeting per year to coincide with the annual audit of the nuclear program which usually occurs during the first quarter of the year. Members of the committee will continue to meet on a more frequent basis to review personnel dosimetry and X-ray issues but these meetings will not be official radiation safety committee meetings. The committee will officially meet additionally if a nuclear issue arises that requires it's intervention or expertise.

We hope that you find the timeliness and the comprehensiveness of our responses acceptable.

If you have any questions or require additional information or documentation, please don't hesitate to contact me.

Mark Perna
RSO
Monongalia General Hospital