

Memo to: James Thompson N.R.C.

From: Harry Palmer

Re: Response to NRC inspection of Kaiser Permanente on June 13-14, 2022

Date: June 15,2022

In the exit conference with James Thompson of the NRC and Stephen Hopkins and Harry Palmer of Kaiser Permanente, one possible violation was mentioned:

One of approximately 100 Written Directives examined showed a prescribed dose of 100mCi and a delivered dose of 51.89mCi. (a difference of 48.1%.)

While greater than a 20% difference, this was not a Medical Event since the delivered dose did not reach the dose level necessary to meet the definition in this post-Thyroidectomy patient.

That being said, this is not our desired standard of care.

In researching the root cause, it became clear that the endocrinologist chose a dose of 50mCi, but the prescribing Nuclear Medicine physician modified the dose to 100mCi. The prescribing Nuclear Medicine physician then wrote a Written Directive for 100mCi on 4/5/22.

That Written Directive was placed at the desk of the lead Nuclear Medicine technologist, where it was inadvertently filed before it was reviewed. The order was placed for the requested dose in EPIC (50mCi).

When the dose was received on 5/18/22, the technologist measured 51.89mCi and recorded this.

When a second Authorized User, present at the administration of the dose that day, he verified the dose in the calibrator and signed for the dose received.

In talking with the Nuclear Medicine physician, she stated that both the dose she prescribed and that delivered were within acceptable though debatable clinical limits and this patient outcome should be acceptable (as there are various clinical references in medical literature).

In looking to avoid the highly unacceptable repetition of this event, the following are considered:

Typically, the Endocrinologist calls for a particular dose which is put into EPIC. The Nuclear Medicine physician, though typically agreeing with that dose, can and will occasionally change the dose to the one that is actually prescribed. The Written Directive is then passed on the chief technologist.

Given that process, the following steps will be implemented or reenforced:

1. THE ORDER FOR THE DOSE SHALL ONLY BE MADE FROM A COMPLETED WRITTEN DIRECTIVE SIGNED BY AN AUTHORIZED USER. **No** order shall be made from dose levels in Epic or any other source.
2. The technologist who receives the dose shipment shall thoroughly check the incoming order against the dose specified in the written Directive.
3. The Authorized User at the time of administration shall check the dose received against the dose prescribed on the Written Directive.