# Meeting Minutes: Radioactive Materials Unit

## March 6, 2018

Minutes prepared by: Tyler Kruse
Location: OLF B-145

## Attendance

- MDH Staff:
  - Sherrie Flaherty, Supervisor, Radioactive Materials Unit
  - Lynn Fortier, Radiation Protection Specialist
  - Tyler Kruse, Radiation Protection Specialist
  - Jaqueline Cavanagh, Policies and Rules Analyst
  - Mary Navara, Manager, IER Section
  - Norma Leland, Office Administrative Specialist
  - Kelly Smeltzer, WebEx Coordinator
- WebEx 28 lines open

## Decisions Made

- See Action Items below

## Action Items

- Add a training and experience pathway to the definition of an authorized physician. – **Done**
- Add a training and experience pathway to the definition of a Qualified Medical Physicist - **Done**
- compare the definition of a Qualified Medical Physicist with the AAMP definition to make sure they are consistent – **Done**
- Define “weekly” with regard to the medical event definition. **Not necessary, weekly requirement replaced with a dose per fraction requirement**
- Consider reverting the weekly dose medical event criteria, back to the single fraction definition in past versions of the regulations. – **Done**
- Contact Stakeholder about concerns involving medical event definition. – **Done**
- Replace the term “written order” with “prescribed dose” in the definition for medical events. - **Done**
- In reference to letter D of the medical event definition (treatment with the wrong treatment modality or energy): Would the term “particle” be more applicable than “modality?” – **kept as modality**

- Discuss the potential for HIPA issues when asking the registrants to notify the manufacturer of medical events as required by 4733.0525. The Stakeholders feel this is an FDA issue, not MDH. – **Removed the requirement for this to be in the procedure.**
- Review the operator and physicist requirements to ensure we are not inadvertently denying the physicists from operating the machines for QAQC purposes. – **No changes made**
- Verify that 4733.2010 Subpart 1. Item N. (daily, weekly, and monthly equipment performance tests) refers to the appropriate rule part. – **All internal rule references will be reviewed at a later date**
- Include a certified health physicist as a pathway for training for Radiation Safety Officers. – **Done**
- Allow qualified RSOs to attest to the competency of a proposed RSO. – **Done**
- Include reviewing dosimetry records (item C.) and radiation surveys (Item B.) from the Qualified Medical Physicist's responsibilities (4733.0410 Subpart2). Add them to the RSO responsibility to "perform, or arrange to have performed" (4733.0405 subpart 4. H.) – **Done**
- 4733.0410 Subpart 4: Consider allowing a designee, who the Qualified Medical Physicist has deemed qualified, to verify treatment plans. – **Done**
- Consider requiring verification of treatment plans prior to 1st treatment on all plans (4733.0410 subpart 4) – **No change made**.
- Investigate notifications required under 4733.0150 to determine if it is necessary. – **Changed to notifications required only if a dose to the member of the public**
- Consider including ABHP or ABMPs as qualified for shielding plans. - **Done**

## Agenda and notes

Presenter: Sherrie Flaherty

- 1:00 - 1:10 Introduction
- 1:10 – 2:50 Discussion and Questions
- 2:50– 3:00 Wrap up and Next Steps

### Rule Part and Discussion Points

1. 4733.0105 Definitions
    - Authorized Physician
    - Qualified Medical Physicist
2. 4733.0107 Notification and Registration Requirements
3. 4733.0180 Medical Events
4. 4733.0210 General Equipment Operator Requirements
5. 4733.0215 Records
6. 4733.0405 Radiation Safety Officer
7. 4733.0410 Qualified Medical Physicist
8. 4733.0435 Written Orders

## Next Meeting

Date: April 17, 2018
Time: 1:00 pm

Location: OLF-B145
Agenda items:

# Meeting Notes

## 4733.0105 Definitions

### *Authorized Physician*

- MDH: Reviewed the definition and explained that this is the person who signs the written order. This is consistent with CRCPD suggested state regulations.
- Comments:
  - **Stakeholder**: There is no training and experience route included. Will there be a training and experience route?
    - **MDH**: We left this out intentionally. We would like stakeholder comments as to if it is necessary.
    - **Stakeholder**: there is a year period where an AP would be working, not under the supervision of a board certified AP, and would not yet have board certification. Therefore, a training and experience route would be necessary.
    - **Stakeholder**: A new graduate would be signing orders, while not technically certified yet.
    - **Stakeholder**: We also have APs who sign prescriptions, and are new graduates who have not completed their boards yet. We would like to see a training and experience pathway.
    - **MDH**: We will consider adding a training and experience pathway.
  - **Stakeholder**: How many people are currently authorized under part B (Certification in Radiation Oncology by the American Osteopathic Board of Radiology)? Is it necessary to include? I have never seen one.
    - **MDH:** We don't have that information
    - **Stakeholder**: We have one Authorized Physician that would fall under this category

### *Qualified Medical Physicist (possibly adding grandfather clause)*

- MDH reviewed the definition of a QMP. Explained that we are requiring board certification according to the CRCPD suggested state regulations with no training and experience pathway. We removed a large portion of the definition that allowed very specific, non-board certified QMPs. For circumstances where this decision would exclude a current QMP, MDH would issue a variance.
- Comments:
  - **Stakeholder**: Who would be reviewing the qualifications for a variance?
    - **MDH**: Our unit staff would be reviewing the individual's credentials and granting the variances
  - **Stakeholder**: Can we add a training and experience pathway for this definition as well?
    - **MDH:** we will consider adding this pathway.
  - **Stakeholder**: In my experience, variances are a temporary authorization intended to fill in the time gap for an individual who is in the process of becoming compliant. Is this the case?
    - **MDH**: MDH has the ability to grant a variance for any amount of time and for reasons we deem necessary. It is not MDH's intent for this rule to exclude any current QMPs.
  - **Stakeholder:** Previous versions of the rule had the AAPM definition included.

        - **MDH**: We will compare our definition with the AAMP definition to make sure they are consistent

### *Medical event*

- MDH provide the definition of a medical event and asked for comments
- Comments:
    - **Stakeholder**: What is the definition of "weekly?" Is it Monday through Sunday, or 7 days from the time the treatment was delivered?
        - **MDH:** We interpret "weekly" to mean 7 consecutive days. We can define this if needed.
        - **Stakeholder**: 7 consecutive days makes more sense as most departments are checking charts every 5 fractions.
        - **MDH**: We have a section about chart checks.
        - **Stakeholder**: We would be fine with a week defined as 7 consecutive days.
    - **Stakeholder:** Why MDH eliminate medical events for a single fraction deviation and focus more on a weekly dose?
        - **MDH:** We based this on decisions made by other jurisdictions and a general assumption that this approach is preferred by the regulated community.
        - **Stakeholder:** Prefer the single fraction medical event criteria to the weekly. In situations where a large dose is delivered over few fractions, a fairly large deviation in dose for a single fraction would not meet the definition of a medical event if we are only considering on a weekly basis as all fractions could be delivered within one week.
        - **WebEx Submittal:** in favor of going back to the single fraction dose definition.
        - **MDH:** We will consider reverting the weekly dose medical event criteria, back to the single fraction definition in past versions of the regulations.
    - **Stakeholder:** is there a definition for treatment site
        - **MDH:** No.
        - **Stakeholder:** it is subjective. A Medical event should be defined as under dosing or overdosing. How to define it radiobiologically is not known and may flirt with medical decisions.
        - **Stakeholder:** how would we be able to determine the radiobiological effects in a short amount of time in order to report it?
        - **MDH:** that is why we use more general medical event definition criteria.
    - **Stakeholder**: Why do we have treating with the wrong energy for a medical event
        - **Stakeholder**: the effects of treating with the wrong energy are not detrimental
        - **Stakeholder**: As long as the monitor units are correct.
        - **Stakeholder**: don't think this is necessary for this to be a medical event
        - **Stakeholder:** Would it be a medical event if: the written order specifies an energy, the dosimetrist will uses a different energy during planning, and the written order wasn't amended.
        - **MDH:** it would depend on what you consider the "written order." The Authorized Physician must sign off on the change made by the dosimetrist prior to treatment, and generally would when they approve the plan. This approval is what we consider the written order in most cases. Not the original prescription.

        - **Stakeholder:** physicians do not necessarily dictate what energy is used to treat. It is done during planning. In a situation where everything is done according to the plan, but written order originally signed by the physician is different from what is planned, it is a documentation error.
        - **MDH**: this will not be an issue as long as the Authorized Physician has signed off on the final plan with the energy that will be used during treatment.
    - **Webex question:** when the plan is missing information, a plan would lead to a medical event.
        - **MDH:** we are attempting to cover this without getting into the realm of a medical decision.
        - **Stakeholder:** quality of dosimetry is a quality issue for each institution
        - **Stakeholder:** (clarifying) there are instances where plans were signed off, that were incorrect that were clearly medical events. However, the definition did not capture them.
        - **MDH:** will have a discussion with this stakeholder about concerns involving specific facilities. We may need to add the term "written order" to the definition rather than "prescribed dose."
        - **Stakeholder:** agrees with taking out "prescribed dose" and using "written order." Written order definition would clarify the definition of medical event, and all items required in a written order are consistent and understood in the regulated community.
        - **MDH:** agree
    - **Stakeholder**: in reference to letter D (treatment with the wrong treatment modality or energy): Would the term "particle" be more applicable than "modality?"
        - **MDH:** We will look into this

## 4733.0107 Registration Requirements

- Different process. Registration will now include an application process and submittal of program information. Including authorized physicians, qualified medical physicists, RSOs, and each's qualifications. Showed an example of what a registration will look like.
- Comments:
    - **Stakeholder**: Does this include cone beam CT and OBI etc.
        - **MDH:** Yes. We would like to list all of those things to keep them off the X-ray unit's plate.
        - **Stakeholder**: would we need to track tube changes on OBI system?
        - **MDH:** We will not be tracking tube changes. Only tracking changes in equipment.
        - **Stakeholder:** Do we need to register the OBI with the X-ray department too?
        - **MDH:** At this point, yes. There is not currently a way to separate this completely.
        - **Stakeholder:** the $500 fee includes everything for the entire facility. Our facility would prefer to only register the [radiation therapy] equipment with therapy unit. Having the X-ray track these parts of the system in addition is redundant.
    - **Stakeholder:** What is the lag time on setting this up? How long do the registrants have to get this set up?
        - **MDH:** that is defined in rule. Registrants will have 120 days to get your application to us from the day the rule is implemented.
    - **Stakeholder:** when intending to purchase and construct new facility, it states the registrant must submit an application 60 or 90 days prior. Are you asking for our opinion on this?
        - **MDH:** yes, what is reasonable?

        - **Stakeholder:** I would like it to allow as much time as possible for the registrant to submit documentation. 60 days seems reasonable as long as MDH this allows MDH enough time to approve the application.
    - **Stakeholder:** Will it be possible to register online?
        - **MDH:** we are planning to together guidance documents and have registrants submit electronically.
    - **WebEx Question**: will registration include treatment-planning systems?
        - **MDH:** we had not considered the treatment planning system.
        - **Stakeholder:** Other states do not have the treatment planning system included.

## 4733.0180 Medical Event Notification

- This is similar to the current regulations. We have include a section of patient intervention, but only if the intervention results in permanent functional damage.
- Comments:
    - **Stakeholder:** [note: there are two subpart 4's for this section]. Refereeing to the second subpart 4, item H. Notifying authorized physician, should this be the referring physician?
        - **MDH:** Yes, referring physician.
    - **Stakeholder:** an medical event require us to contact the state, make a report and contact the AU and the individual. Are we assuming a medical event has caused or may cause serious medical damage/issues?
        - **MDH:** we do not make that determination the AU does.
        - **Stakeholder:** we could figure out ways to make things that meet the definition of medical events, that we could fix and have the same biological outcome as the original plan.
        - **MDH:** A medical event does not mean that there are detrimental effects on the patient. However by reporting it there is an opportunity to identify issues in the quality management program and ensure they done happen again.
        - **Stakeholder**: Thanks for clarifying.
    - **Stakeholder**: 4733.0525 requires the registrant to include notifying the manufacturer of medical events in their procedures, is this necessary?
        - **MDH:** this would only be required if the event is machine related. We do not intend to have you notify the manufacturer if there is an medical event that is not equipment related.
        - **Stakeholder:** Notifying the manufacturer may cause issues with HIPA compliance if manufactures are getting HIPA protected information. I believe this is an FDA issue that should not be addressed in this rule.
        - **MDH**: This is part of the emergency procedures (which is not on the agenda for this meeting). We will look into FDA coverage of this requirement. We will discuss this issue further in the next meeting.

## 4733.0210 General Equipment Operator Requirements

- Our intent is to separate operators for human use and veterinary use. We are proposing that operators bust be ARRT certified for human use, we will accept other equivalent certifications.
- Comments:

- **Stakeholder**: Does this include operating for QAQC testing?
  - **MDH**: This section is in reference to the operator during actual treatment. MDH will review the operator requirements and physicist requirements to ensure we are not inadvertently denying the physicists from operating the machines for QAQC purposes.

## 4733.0215 Records (all the required records and retention)

- We put all record requirements into one section. In addition, each section that requires records to be kept will refer back to the record section.
- Comments:
  - **Stakeholder**: Subpart 1. Item N. (daily, weekly, and monthly equipment performance tests) does not refer to the proper rule part.
    - **MDH**: We will correct this.

## 4733.0405 Radiation Safety Officer

- Reviewed the Radiation Safety Officer training and responsibilities from 4733.0405;
- Comments:
  - **Stakeholder:** Can we include a certified health physicist as a pathway for training for Radiation Safety Officers?
    - **MDH:** Yes.
  - **Stakeholder:** The rule requires the radiation safety officer preceptor attestation be signed Medical physicist. Can we include attestations signed by qualified RSOs?
    - **MDH:** Yes.
  - **Stakeholder:** There are things under medical physicist that are typically done by radiation safety staff. Such as: reviewing dosimetry records and radiation surveys. I believe these items should be listed under the RSO responsibility to "perform, or arrange to have performed" (4733.0405 subpart 4. H.)
  - **Stakeholder**: Agree, take B and C from the physicist's responsibilities (4733.0410 Subp. 2) and give them to the RSO under 4733.0405 Subp 4 H.
  - **MDH**: we will make this change.

## 4733.0410 Qualified Medical Physicist

- Reviewed the Qualified Medical Physicist training and responsibilities from 4733.0410;
- Comments:
  - **Stakeholder**: 4733.0410 Subpart 4 states that a Qualified Medical Physicist must verify treatment plans. This is not necessary and should be changed to a qualified medical physicist or a designee that the qualified medical physicist has deemed qualified. Also thinks verification of treatment plans this should be done prior to 1$^{st}$ treatment of all plans.
  - **MDH** we will consider that.

### 4733.0435 Written Orders

- Reviewed quality management program and written orders. Therapy and simulation. Asked for comments about who is responsible for each order.
- Comments:
  - **Stakeholder**: in our facility, the physician creates a separate simulation written order and therapy written order.
  - **Stakeholder:** This will be the same at all facilities because of billing.
- **Stakeholder:** page 46 subpart 4: "What?"
  - **MDH:** This comment was not intended to be published in this draft.

## Open discussion:

- **Stakeholder:** Why are we requiring notification of non-medical events (4733.0150)? What is the purpose?
  - **MDH:** this is likely for protecting a member of the public from exposure due to a non-medical event. We will look at this rule, and where it originated to determine if it is necessary.
- **Stakeholder:** I would like MDH to consider ABHP or ABMPs as qualified to do a shielding plan.
  - **MDH:** we will consider this.
- **Stakeholder:** are you looking to define what monthly and annual mean?
  - **MDH:** We can if we need to. We will take your suggestions and consider a definition
  - **Stakeholder**: has seen in other regulations that years mean between 10 and 14 months
  - **MDH:** A definition will need to be consistent between X-ray, RAM and Therapy. Submit your suggestions and we will consider.

625 Robert Street North
Minnesota Department of Health
PO Box 64975
St. Paul, MN 55164-0975
651-201-4400
health.ram@state.mn.us
www.health.state.mn.us

03/06/2018