Duran-Hernandez, Doris

Subject: FW: Docket ID NRC-2016-0122 State of Washington Comment for DRAFT NuReg 1556 Volume 9 Revision 3

Attachments: State of Washington Comments for NuReg 1556 Volume 9 Revision 3 DRAFT February 2017.pdf

From: Demaris, Curt (DOH) [mailto:Curt.Demaris@DOH.WA.GOV]
Sent: Wednesday, February 15, 2017 4:25 PM
To: Bladey, Cindy <Cindy.Bladey@nrc.gov>
Cc: Lawrence, Craig (DOH) <Craig.Lawrence@DOH.WA.GOV>; Fordham, Earl W (DOH) <Earl.Fordham@DOH.WA.GOV>
Subject: [External_Sender] Docket ID NRC-2016-0122 State of Washington Comment for DRAFT NuReg 1556 Volume 9 Revision 3

Cindy:

Attached are the state of Washington comments following review of the draft document identified in the subject line.

The state of Washington thanks you for this opportunity to comment.

Please feel free to contact us with any questions.

Thank you.

C. DeMaris
Medical Program

12/6/2016
82FR 87978
6

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM-03
Add= K. Tapp (KNS1)

State of Washington Comment

Draft NuReg 1556, Volume 9, Rev 3: Program Specific Guidance About Medical Use Licenses

Please include Docket ID NRC-2016-0122 in the subject line of your comments.

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Cindy.Bladey@nrc.gov

For any questions about the material in this report, please contact: Katie Tapp, Ph.D., at 301-415-0236 or by e-mail at Katherine.Tapp@nrc.gov.

Disclaimer: "This draft does not include any revisions associated with the proposed rule "Medical Use of Byproduct Material-Medical Event Definitions, Training and Experience, and Clarifying Amendments" as that rulemaking is not completed. The proposed rule and proposed changes to NUREG-1556, Volume 9, associated with the proposed rule were published for public comment in the Federal Register (79 FR 42409, 79 FR 42224) on July 21, 2014. Comments received on those changes are being considered by the NRC staff separately. If the proposed rule becomes final, the **proposed revisions to NUREG-1556, Volume 9 addressing the implementation of the proposed rule will be incorporated into this NUREG-1556, Volume 9, Revision 3 before its final publication**."

Some of the comments in this document will reflect precisely those changes. In light of your most recent correspondence (quoted above, bold added by us) we agree with the not-yet official proposed changes, and you may feel free to ignore those comments which refer to those new/proposed medical reg revisions.

U–3 Activities **Using or Involving** Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child...

Just generally, throughout the document, we like all the embedded links in the electronic version (though, they do not seem to be actual links in this document).

This document does not seem to address in any way the authorization or responsibilities of the Associate RSO.

ALARA as low as **is**—(delete the "is") reasonably achievable. This appears throughout the document, e.g. 8-1, lines 10, 15, & 17. 1.3.1 does not use the "is".

The definition of "AU" now appears to have been further parsed into "AUD, AUS, AUT". Is this really necessary?

Table 1-1: 8.10.5—Why are "Spill/Contamination Procedures" indicated for Parts of 10 CFR 35 which apply only to use of sealed sources?

Generally, why not use the term "Native American" tribe etc. instead of the technical misnomer "Indian"?

4-1, line 7: the word "materials" is used twice in a row, should delete one.

5.4, line 19: "CD-ROM"? Does anyone still use this media?

5.4, line 20: The "Packing Slip Wizard" referenced on your website does not seem to allow for Windows 10, the OS of current use/choice for most people.

6-2, line 9: Do you mean "personnel", or "personal"?

8-4, line 6: Does this apply to any and all materials licensees, or just those with Category 1 or 2 material?

8-5, line 13: Why no actual direct link to 10 CFR 37?

8-12, line 7: I think the word "incident" should be "incidental"

8-13, line 25: "...licensee**'s** procedures".

8-14: I thought NRC was discontinuing the dual/unnecessary requirement for the written attestation if the applicant is/was already appropriately board-certified.

8-15: What happened to "conducting leak tests" as necessary and maintaining inventory?

8-19, line 26: refers to other "...criteria in 10 CFR Part 33....". However, 10 CFR 33 has no specific criteria related to qualifications of an RSO for a Broad license except for a Broad A, and even that is completely generic; "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". Not really any additional "criteria" in 10 CFR 33.

8-20, Line 33: "...can be found **at (or "in")** the Medical Uses Licensees Toolkit..."

8-30, Lines 28 & 33: "a licensee **who** permits..."

8-31, Lines 8 & 12: should be "or" (or even "and/or") Category 1 "or" Category 2....

8-32, Line 11: Somehow this line just doesn't read "right"...

8-33, Line 9: How can they provide "survey results" if they have yet to receive a license authorizing them to possess the material which would provide those survey results?

8-35, Line 4: Is capsule form of NaI I-131 accurately described as "volatile"?

8-38, Line 6: the "or" should be changed to "and", since there can be no "scale used" indicated if the drawing is not to scale.

8-44, line 36: "there are hazards associated with volatile iodine in capsule form...". We currently do not require bioassay for I-131 if the sole use of that nuclide is in capsule form only. Does this mean NRC is changing their mind about the potential volatility of I-131 in capsule form with regard to the requirements for bioassay?

8-45, line 3: Is anyone actually installing and using teletherapy in the U.S. anymore, or is this mainly for those who still have these old units as they are cycled out of their useful working life? We have had no actual teletherapy units in our state for years.

8-45, Line 28: New and good information related to PDR licensing. We have none of these in our state at this time, but the warning systems and interlocks appear even more stringent than for regular HDR.

8-46, Line 37: Does this apply to all "remote afterloader facilities", or just HDR?

8-47, Line 4: Does this prohibition apply to all "X-Ray machines", or are simulators exempted?

8-51, Figure 8-5: Need the closing parentheses after the 10 CFR 20.1201 reference for the bolded "Dose Limits for Adult Radiation Worker".

8-52, Line 14: Could add "(OSL)".'

8-52, Line 21: Is there no instruction or provision here for the latest electronic dosimeters which are used and read via the internet?

8-53, Line 1: it should be "their" procedures, not "its" procedures...

8-53, Table 8-2: Actual web links to each of these documents would be very beneficial.

8-59: Should there also be a reference here to the NSTS/Inventories?

8-62, Lines 11 & 17: Is it still five years? Thought it was now 7 years.

8-67, Line 5: It says "No response is necessary if leak testing is performed in-house", but if it is performed in-house, don't they need to submit procedures and forms for leak testing, to be reviewed and approved by the licensing agency?

8-70, Line 7: should this also include reference to 10 CFR 35.604?

8-75, Line 29: Seems redundant after lines 27 & 28.

8-76, Chart: Does this section really apply to 10 CFR 35—400, 500, 600, & 1000 since those are sealed source only and, as noted, leak tests are usually the first and only line of defense for potentially leaking sealed sources?

8-78, Line 29: Does "written report" include properly signed email reports?

8-80, Line 8: A link to this document would be potentially helpful.

8-81, Applicability: Do persons licensed under 10 CFR 35.400 ever have this amount of aggregated activity, to put them into a Category 2 or Category 1 possession?

8-85, Line 12: Could add "10 CFR" in front of the numerical reference.

8-85, Lines 18 & 19: I think that should be "explantation", not "explanation".

8-86, Line 6: Duplicate "Subpart K" reference, should delete one.

8-86, Line 9: Links to each of the listed references would be good.

9-2, Line 7: As long as there is no requested change to the AUR's current authorization(s).

11-1, Lines 12 & 13: should be "principal", not "principle". Got it right in Line 17, though.

A-2, Line 11: Could add "termination" and/or "degradation of current job status".

C-1, Line 17: "Appendices", not "Appendix", since the reference is to plural/multiple appendices.

C-2: We like the top check boxes to indicate whether or not material is security-related.

C-2, Sm-153 box: Wouldn't this be outpatient only, since it's a beta-emitter?

C-3 & C-4: Ba-133, Cs-137, & Gd-153—Aren't these more "QA" sources rather than sources used for "diagnostic medical use"?

C-7, Last Line: Could use "their" rather than the cumbersome "his/her".

C-12, Item 8, last statement: should this be "...the type **and** level of radiation..."?

C-12, Item 9, first sentence: Since "alpha, beta, and gamma" covers the entire spectrum of potential ionizing radiation emissions, is there any real need here to differentiate, or can you just remove those subcategories?

C-14, Item 10: Leak Tests—"No response is necessary if leak testing is performed in-house". Is this true? If performed in-house don't you need to review procedures, calculations, nuclide standards, report forms, action levels, etc.?

C-16, Appendix N line: No Emergency Procedures for brachytherapy, HDR, or GK use?

D-2, Lines 23/24—"...comparable linear accelerator experience...". What, exactly, would this be? Is experience with a linear accelerator in any way "comparable" to using a machine with a radioactive source?

D-2, Line 36: "...provide a **current and complete** copy of the license".

D-4, Line 4: Add "who" to the end of that line.

D-5, Line 37: Should this also include "regular" NRC medical licenses?

G-1, Line 5: Should provide examples/links to examples of "nationally recognized standards".

G-1, Line 16: Could delete "...to another building...".

G-1, Line 18: Is Co-57 considered a long-lived source?

G-1, Line 35: Is this the *only* nuclide/method approved?

G-2, Line 15: This is good info to have codified into the NuReg.

G-3, Line 14: Could change "worst" to "greatest".

H-1, Line 9: Could use "The test" at the beginning of this line.

H-1, Line 29: This assumes all licensees are using remote video for viewing, it is possible there are some licensees who still have (leaded) glass windows providing a direct line of sight from the operator console into the treatment rom.

H-2, Line 6: "...the presence **and current calibration** of the meter..."

I-1, Line 4: Could add "Agreement State" to this line/list.

I-1, Line 9: Delete "is".

I-1, Line 11: add "or stored" to the end of this sentence.

I-1, Line 26: "...are **reviewed** and maintained".

I-1, Line 27: "Properly secure radioactive material **from unauthorized use or access**".

I-2, Lines 3, 5, 9, 20, 24, 31 & 33: Add "Agreement State" to the list.

I-3, Line 14: add "...or Agreement State regulatory agency".

J-2: Could also add the worker's right to contact the regulatory agency with concerns.

J-3, Line 20: Don't the latest GK's, the Perfexion, not use helmets?

K-1, Line 33: Must also be NIST-traceable.

K-5, Lines 8 & 9: This could well be correct, I am not familiar enough to know, but should that really be "80%" and then "20%", or should it be 20% and then 80%?

K-6, Line 14: Why the "exposure reading indicated..." when every survey instrument has an assigned/designated "battery" good/not good area on the dial/face?

K-7, Line 15: Could actually reference Ba-133 here.

K-7, Footnote: An actual definition of "intrinsic efficiency" would be helpful here.

K-7, Line 17, and K-8, Line 11: Is there any other official body besides NIST for this?

K-8, Line 28: Shouldn't there be a date associated with this publication?

L-4, Line 3: Could you add the requirement for the annual Inventory Reconciliation here?

L-6, Line 33: "...controls and**/or** maintains constant...."

L-12, Line 7: Also protected from unauthorized access or removal?

L-12, Line 23: The reference to "(C)" and "(D)" is unclear/unexplained.

L-13, Line 13: Two labels—on opposite sides not to include the bottom.

L-14, Line 7: Could put "(HDR)" after "...high dose-rate".

L-15, Line 5: Should be a proviso here for the Perfexion models which do not require all these things.

M-1, Lines 1, 2,3, 4, & 8: "...occupational dose **monitoring** program..."

M-1, Line 25: "...**ionizing** radiation".

M-1, Line 28: "their" dose, rather than "his or her" dose.

M-1, Line 34: delete "is"

M-1, Line 39: "for" instead of "on".

M-1, Line 41: change "in" to "as part of"

M-2, Line 8: is there/should there be, a reference here to appropriate protection factors?

M-2, Line 12: "...for adults with a **projected or potential** annual dose..."

M-3, Line 6: "who", not "that".

M-5, Line 15: add "and" to the end of the sentence

M-5. Line 26: "Terms", or "Levels"?

M-6, Lines 7, 8, & 9: should provide a definition, or link to definition, here for stochastic and nonstochastic.

M-6, Line 23: should add "baseline, routine, special, and termination" bioassay designations to program requirements

M-6, Line 26: Should add Reg Guide 8.20, Rev 2 to this list of additional guidance.

N-3, Lines 22 & 23: double reference here to bioassay samples, can delete one.

N-4, Line 13: "reasonably", not "reasonable".

N-5, Lines 19 & 20: "explantation", not "explanation".

O-1, Lines 21 & 22: "Department", not "Division".

Q-4, Line 1: You have used "(iii)" twice, the second one should be "(iv)".

S-1, Line 21: "dosage-rate treatment", or "dose-rate treatment" such as HDR?

S-2, Line 14: should end with a colon, not a period.

S-2, Line 20: add "but must be available for inspection".

S-4, Line 14: add "or" to the end of the line

S-4, Line 21: there is/should be no "t" in "Perfexion".

S-5, Lines 12 & 14: add "or Agreement State regulatory authority".

T-1, Line 21: "...when handling **or injecting** radioactive material"

T-1, Line 24: A worthwhile ban, but our licensees tell us that **no one** pipettes by mouth anymore.

T-2, Line 24: add "or Agreement State" to the end of this line.

U-1, Line 22: "[0.5 rem] **limit (or threshold)**..."

U-1, Line 29: Delete "is".

U-1, Line 35: the extra "(I-131)" is superfluous.

U-2, Line 7: the symbol for specific gamma ray constant is missing the little overhang on the right.

U-5, Table U-1: Why is Pd the only nuclide not spelled out (column size limitations?), and why is Cs-131 implant not in this table?

U-6, Table U-1: first nuclide, strontium, is misspelled. Also, there are diagnostic nuclides listed in this table and I thought this was for therapy only.

U-7, Line 32: A link to this article would be helpful.

U-8, Table U-2: Strontium is again misspelled.

U-9, Table U-3: "Sulfur" colloid, not "sulfer".

U-15, Table U-5: Strontium is again misspelled.

U-15, Table U-5: why is Cs-131 implant not in this table?

U-21, Line 5 & U-24, Line 29: I think this should be "metasteses" (plural), not "metastasis" (single).

Appendix U, in general: While this Appendix appropriately acknowledges that the regulatory authority cannot dictate all conditions for a patient's release, this would be a good place to insert a strong suggestion that therapy patients not spend any of the time immediately following the administration of their therapy in a hotel.

V-3, Line 21: "...removed from the client**'s facility**..."

V-6, Line 13: "dosage-rate treatment", or "dose-rate treatment"?

V-8, Line 15: Delete "is".

V-10, Line 30: Change "they" to "it".

W-1, Line 16: Delete "is".

W-1, Line 22: Delete "store" (redundant).

W-1, Line 30: add "and" just before the final "the".

W-1, Line 33: should "sufficient" be changed to "measureable"?

W-4, Line 3: Is there an actual upper limit of 1 Ci disposal "for all other radionuclides combined", even if the sewerage totals would allow more than that?

Y-1, 5th box: Is there no written report required when a package is received which exceeds 10 CFR 71 levels?

Y-2, 4th box: Are there ever any "planned" fires or explosions?

Y-2, next-to-last box: Since there is no "intended" permanent functional damage, could delete "unintended".

Z-5, first bullet under "Provisions for Control of Contamination on Radioactive Material Packages Prior to Shipment"—"reasonably", not "reasonable".

Z-5, directly under first orange header: "reasonably", not "reasonable".

Z-6, second bullet under last orange header: "in" the transport vehicle, not "on".

AA-1, line 6: Could change "apply" to "prevail" or "take precedence".

AA-2: Should add RG 8.20, Rev 2 to this list.

AA-2, Line 7: does the RG for reactors really apply in any way to this medical guidance?

AA-3, Line 35: should be "Molybdenum-99 breakthrough...", not "Molybdenum-90..". This is also an error in the listing of the same IN on the NRC website (though the title of the actual document is correct once you get to it).