UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
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ARLINGTON, TEXAS 76011-4511

EMAIL

Name:	Yongli Ning, MS, AMP, RSO	License: 50-17838-01 Docket: 030-13426
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From:	Jacqueline D. Cook	
Date:	May 4, 2015	
Subject:	Application dated November 4, 2014, and e-mail resubmittal dated April 30, 2015, and received May 1, 2015, for License Renewal	
Pages:	4	

Mr. Ning

Per your application dated November 4, 2014, and e-mail resubmittal dated April 30, 2015, and received May 1, 2015, the items on the next pages are a request for additional information (deficiency) which require your response. **Please respond to this e-mail by Monday, May 18, 2015. Please contact me and let me know if you are unable to submit your response by this date and suggest an alternate date to respond.** Our fax number is (817) 200-8263. You may respond by e-mail in pdf format if you'd like. My email address is Jackie.Cook@nrc.gov. When responding to this e-mail, please include the license, docket and control numbers located at the top of this page.

Thanking you in advance for your cooperation, assistance, and prompt response in this matter.

/RA/
Jacqueline D. Cook
Senior Health Physicist

PUBLIC
☐ Immediate Release
☑ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: _____ Date: 5/4/15

1. Please note that in your email resubmittal package dated April 30, 2015, and received May 1, 2015, Providence Alaska Medical Center's Radiation Safety Program 2014, you gave us an unsigned memo of the Delegation of Authority dated February 15, 2008.

   Please submit a more current delegation of authority for Mr. Ning as Radiation Safety Officer (RSO). You can use the model procedure found in Appendix I of NUREG-1556, Vol. 9, Rev. 2. (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/).

2. Submit a clearer and larger diagram which should include:

   A. Scale used

   B. Location, room numbers and principal use of each room or area where byproduct material is prepared, used or stored.

   C. Location, room numbers, and principal use of each adjacent room, including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and

   D. Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

3. Please submit a description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

4. Although you checked the box for Item 9: Dose Calibrator and Other Dosage Measuring Equipment Table C.3, page C-19, "We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures", you also checked the box for Item 9: Dose Calibrator and Other Dosage Measuring Equipment Table C.3. page C-19, "A statement that: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation." Please note that these suggested responses are **"OR"** statements.

   Please clarify your response.

5. Please submit procedures for periodic spot-checks for your remote afterloader unit as required by 10 CFR 35.643 for review and approval.

6. You checked the box for Item 9: Other Equipment and Facilities, "attached is a description, identified as Attachment 9.4, of additional facilities and equipment", page C-19.

   Please clarify this statement.

7. Because you are authorized for manual brachytherapy use in accordance with 10 CFR 35.400, please provide a description of the emergency response equipment.

8. In Table C.2., you didn't check that you had fluorine-18, oxygen-15, or carbon-11. Please clarify if you are using PET radionuclides.

   However, you checked the box for Item 9: Other Equipment and Facilities, page C-19 "for PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, we are providing a description of the additional facilities and equipment for these uses".

   Please clarify this discrepancy. If you are using PET radionuclides, please provide the description as requested.

9. Although you checked the box for Item 9: Other Equipment and Facilities, page C-19 indicating that you provided a description of your remote afterloader facilities and looked at Providence Alaska Medical Center's Radiation Safety Program 2014, we were unable to find this information.

   Please explain.

10. Please provide a description of the following:

    - Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
    - Area radiation monitoring equipment;
    - Viewing and intercom systems;
    - Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room;
    - Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and
    - Emergency response equipment

11. Please submit safety procedures required by 10 CFR 35.615.

12. Although you checked the box for Item 10: Safety Procedures and Instructions Table C.3, page C-20, A statement that "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 2, 'Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Medical Use Licenses.'", you also checked the box for Item 10: Safety Procedures and Instructions Table C.3, page C-20, "A description of an alternative method for demonstrating compliance with the referenced regulations" Please note that these suggested responses are **"OR"** statements.

    Please clarify your response.

13. Please clarify who installs, maintains, adjusts, repairs, and inspects the specific therapy device (HDR) possessed by you.

14. You checked the box for Item 11: Waste Management Table C.3, page C-21, "attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004)".

    Please clarify your response.

15. You checked the box for Item 11: Waste Management Table C.3, page C-21, "attached is a request to receive potentially contaminated radiation transport shields from consortium members receiving PET radioactive drugs non-commercially transferred under 10 CFR 30.332(j) authorization".

    Please clarify your response.

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