UNITED STATES
**NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 28, 2011

Docket No. 03029017 License No. 47-17725-02
Control No. 575340

Rocco Massey
Chief Executive Officer
West Virginia Appalachian Regional Healthcare, Inc.
dba Beckley Appalachian Regional Hospital
306 Stanaford Road
Beckley, WV 25801

SUBJECT: WEST VIRGINIA APPALACHIAN REGIONAL HEALTHCARE, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 575340

Dear Mr. Massey:

This is in reference to your application dated June 27, 2011 requesting to renew Nuclear Regulatory Commission License No. 47-17725-02. On April 24, 2002, NRC published new medical regulations in 10 CFR Part 35. These regulations became effective on October 24, 2002. Concurrent with the issuance of the new medical regulations, NRC published NUREG-1556, Volume 9, Rev 2, http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/ "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." Please use NUREG-1556, Volume 9, Revision 2, in preparing your responses to this letter. In addition, you will note that new Part 35 and the NUREG generally do not require the submission of detailed procedures during the licensing process. As described in the NUREG, in many cases, a licensee is required only to supply a statement regarding the development, implementation, and maintenance of written operating and emergency procedures. Appendix C of NUREG-1556, Volume 9, Revision 2 should be helpful in identifying the information required by NRC to process your request for license renewal.

In order to continue our review, we need the following additional information:

1. To facilitate future communications, please provide email addresses and fax numbers for both you and Dr. Bharat G. Patel, your Radiation Safety Officer.

2. Your license application lists your applicant name as Beckley Appalachian Regional Hospital and the cover letter was submitted on the letterhead of Appalachian Regional Healthcare. Your current license is issued to West Virginia Appalachian Regional Healthcare, Inc. dba Beckley Appalachian Regional Hospital. Please confirm that the current licensee name is still applicable or describe any changes in name and/or ownership. If a change in ownership has occurred, please submit the information listed in NUREG-1556, Vol.15, Appendix F.

3. Your license will be written in a format consistent with NUREG 1556, Vol. 9, Rev. 2. In

your response to this letter please use the format below for Items 5 and 6 of your renewal application:

| Radionuclide | Form or Manufacturer /Model No. | Maximum Quantity | Purpose of Use |
|---|---|---|---|
| Any byproduct material permitted by 10 CFR 35.100 | Any | As needed | Any uptake, dilution, and excretion study permitted by 10 CFR 35.100. |
| Any byproduct material permitted by 10 CFR 35.200 | Any | As needed | Any imaging and localization study permitted by 10 CFR 35.200. |

4. Please state whether you wish to retain your current list of Authorized Users or provide a list of the individuals you request to have on the license as Authorized Users along with either their training and experience (NRC Form 313A) or the license number currently authorizing them for uses requested.

5. Please provide a description of the radiation monitoring instruments (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter, etc.) that will be used to perform radiation level detection, measurement, and contamination surveys.

6. Please submit a detailed version of your facility diagram, that indicates the position of each of the areas described below and describe the type, dimensions, and thickness of shielding that you will use.

    a. Use and storage of Tc-99m generators, if applicable.

    b. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).

    c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. This area should be large enough to handle an accumulation of Tc-99m generators as well as other solid waste. If this area is not located within your main department, describe how you will secure the material.

    d. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, specifically designed PET shielding, etc.).

    e. Location of fume hood, if applicable.

    In addition, identify adjacent areas across the walls from use and storage locations as

well as above and below and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301. Drawings should be to scale with the scale indicated on the drawing and marked as security-related sensitive information. See Section 8.16 Figure 8.1 and Appendix E Figure E.1 of NUREG-1556, Vol. 9, Rev. 2.

7. Your application requests F-18 for imaging and references “PET truck delivery.” Please clarify whether you provide PET services under your license or use a mobile service provider. If you are providing services under your license, please indicate when these activities started and where they occur. If you are using a mobile service provider, please indicate who provides these services.

8. Provide the manufacturer and model number for any sealed sources that do not meet the criteria listed in 10 CFR 35.65 (e.g. greater than 30 millicuries).

9. In accordance with the guidance provided in NUREG-1556, Vol. 9, please confirm whether you request to update to the following commitments found in Table C.3 of the NUREG to develop, document, and maintain written procedures that replace Regulatory Guide 10.8 superceded procedures:

    a. "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.”

    b. "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

    c. "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 Licenses: Program-Specific Guidance About Medical Use Licenses.”

    d. “We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the Requirements of 10 CFR 20.1501 and 10 CFR 35.70."

    e. “We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

    f. “We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

    g. "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with10 CFR 20.1101, that also

meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to Robin Elliott at the Region I Office and refer to Mail Control No. 575340. If you have any technical questions regarding this deficiency letter, please call Robin at (610) 337-5076.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

***Original signed by Sandra Gabriel***

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Bharat G. Patel, M.D., Radiation Safety Officer
Jerome Furrow, Director of Medical Imaging

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**SUNSI Review Complete:** RElliott

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