From: Nguyen, Janice
To: "swells@fghi.com"
Subject: NRC Request for Information - Fairmont General Hospital (Mail Control Number 582144)
Date: Wednesday, January 08, 2014 4:09:00 PM

Licensee: Fairmont General Hospital
License No: 47-17929-01
Docket No: 030-13661
Control No: 582144

Dear Ms. Wells,

Could you please reply back to this email to confirm receipt?

This is regarding the license renewal application for Fairmont General Hospital dated September 12, 2013. The following additional information is needed to allow us to continue our review:

1. You have requested that Mark Perna be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:

a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

2. Please provide facility diagrams of the therapy rooms where prostate seed patients and/or 10 CFR 35.300 therapy patients will be housed if they cannot be released under 10 CFR 35.75, including areas above, beside, and below. Alternatively, you may confirm that you will only treat patients who are releasable under 35.75.

3. Under requested authorized uses, you indicated in-vitro studies. However, in-vitro

materials permitted by 10 CFR 31.11 was not requested on the application. Please confirm that you are not requesting the use of materials permitted by 10 CFR 31.11 for in-vitro studies. Alternatively, you may request this authorization. If so, please indicate what authorized users should be permitted to use this material.

4. Please specify the manufacturer and model number of the survey instrument probes. In order to detect I-125 seeds, it is preferable for the instruments to be equipped with a thin sodium iodide crystal detector probe.

5. On your facility diagrams, please identify adjacent areas, including areas above and below, across the walls from use and storage locations 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.

6. Please indicate what areas are considered to be restricted as defined by 10 CFR 20.1003.

7. Please describe how the area used to prepare and store radioactive material is secured from unauthorized access. 10 CFR 20.1801 requires that licensed material be secured against unauthorized removal from the place of storage. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance over materials in unrestricted areas that are not in storage. In your application you did not indicate how you will secure licensed material.

8. You are requesting to possess and use radioactive materials permitted by 10 CFR 35.200 which now includes positron emitting tomography (PET) radiopharmaceuticals. Your application does not request the use of PET. Please confirm you do not wish to be authorized for the use of PET materials. Alternatively, you may request this authorization and include a list of installed shielding and any specialized equipment specific to 511 keV.

9. Please indicate if there are any required sealed sources that do not fall under 10 CFR 35.65.

10. Please include contact information (i.e. phone number and email address) for your certifying official.

11. Please describe the emergency response equipment available for manual brachytherapy (e.g., lead container, long-handled forceps, etc.).

12. Please indicate if there are any areas used for the storage, preparation, and receipt of manual brachytherapy sources other than the Nuclear Medicine Department and remote decay in storage room. If so, please provide facility diagrams for these areas, indicating what areas are adjacent, above, and below.

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 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 582144.

If we do not receive a reply from you within 30 days, we will assume that you do not wish to pursue your license renewal. Please feel free to contact me with any questions you may have.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement is not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Thank you in advance for your help.

Sincerely,

Jan Nguyen

Janice Nguyen
Health Physicist
Nuclear Regulatory Commission Region I
475 Allendale Road
King of Prussia, PA 19406
(610) 337-5006
FAX (610) 337-5269