



**Stafford Hospital
Center**
MEDICORP

K-3

February 10, 2009

45-31345-01
03032864

Michelle Simmons
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406
Office No.: (610)-337-6921
Fax No.: (610)-337-5269

Reference: Mail control number 143010. Stafford Hospital Center

Dear Ms Simmons,

The following is to request that Wendy Charlton be name the RSO for Stafford Hospital Center and address the following inquiries:

1. 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.
See Radiation Protection Program (pg 2-7) that identifies authority and responsibility of RSO at MHS.
2. 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.
The Radiation Safety committee meets quarterly. There is a member of the management team, at the Administrative Director level, that is required to attend so that authorization to release funds for items and services needed to maintain compliance with regulatory requirements can be approved. The department directors and managers also have signing authority to release funds on a pre-defined scale that may not require the approval of a Vice President.
3. 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).
10 hrs per month RSO will be on site. See contract duties, appendix G. There is an additional consultant physicist who will assist with the performance of various equipment testing, record review, and dose calibrator checks.

143010

NMSS/RGNH MATERIALS-002

4. 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. The Nuclear Medicine Technologist on duty, by virtue of their training, will act as a point of contact in the absence of the RSO. There will also be an Administrator on call for the hospital seven days a week and 24 hours a day.
5. 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.
Arrival time minimally 1hr 15 mins, depending upon traffic. Guaranteed arrival by contract is two hours. Overall availability is 24 hrs by cell phone or home phone
6. We would also like to submit a change of address for Krueger-Gilbert Health Physics, Inc.
1118 Baldwin Mill Road Jarrettsville, Maryland 21084

Please contact Cheri DelaRosa, Licensing and Accreditation Specialist at 540-741-2028, should further information be required.

Very truly yours,



Cathleen Yablonski
Senior Vice President and Administrator

Attachments:
Regulatory Protection Program pages 2-7
Appendix G of contract with Krueger Gilbert Health Physicist

Radiation Protection Program

Radiation Safety Committee

The Radiation Safety Committee (RCS) is a standing committee of the hospital. The details of duties, function and responsibilities of this Committee are described in the following.

Purpose:

To establish a Radiation Safety Committee with responsibility for evaluating all uses of radioactive materials and ionizing radiation for the sole purpose of insuring the safety of patients, visitors, and hospital staff.

Policy:

The Radiation Safety Committee is established as the administrative body responsible for the safe uses (diagnostic and therapeutic) of radioisotopes and ionizing radiation-producing equipment within the Hospital. This committee will include representatives of professional and scientific specialties as recommended by the U. S. Nuclear Regulatory Commission.

Action:

1. The committee shall:
 - a. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;
 - b. Ensure that licensed material is used in compliance with NRC regulations and the institutional license;
 - c. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;
 - d. Establish a table of investigational levels for individual occupational radiation exposures;
 - e. Ensure the safe use of diagnostic radiation-producing equipment operated at the Hospital.
 - f. Identify program problems and solutions.
2. Responsibilities. The committee shall:
 - a. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments;
 - b. Review the training and experience of the Radiation Safety Officer (RSO), proposed authorized users, and qualified users, to determine that their qualifications are sufficient;
 - c. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution.
 - d. Prescribe special conditions that will be required during the proposed method of use of radioactive material such as requirements for bioassay, physical examination of users, and special monitoring procedures.
 - e. Review quarterly the summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

Radiation Protection Program

- f. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g. Nursing, Security, Building Management, Engineering, Medical Administration) are appropriately instructed as required in 10 CFR Part 19.12.
 - g. Review at least annually the radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;
 - h. Recommend remedial action to correct any deficiencies identified in the radiation safety program;
 - i. Maintain written minutes of all committee meetings, including members in attendance and members absent, discussion, actions, recommendations, decisions, and numerical results of all votes taken;
 - j. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.
3. Administrative Information:
- a. The committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter.
 - b. Membership must include an authorized user for each type of use authorized by the license, the RSO, a representative of the Nursing Service, and a representative of management who is neither an authorized user nor an RSO.
 - c. To establish a quorum, one-half of the committee's membership, including the RSO and the management representative, must be present.

ALARA Program

1. Management Commitment

- a. The management of the Hospital, is committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accordance with this commitment, an administrative organization for radiation safety has been formed and has developed the necessary written policies, procedures, and instructions to foster the ALARA concept within our institution. The organization includes a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).
- b. A formal annual review of the radiation safety program, including ALARA considerations is performed. This includes reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- c. Modifications to operating and maintenance procedures and to equipment and facilities are made if they will reduce exposures unless the cost is considered to be unjustifiable. Management will demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, management will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably

Radiation Protection Program

achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.
3. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority (The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

1. The RSC will delegate authority of the RSO for enforcement of the ALARA concept.
2. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
2. The RSC will perform a quarterly review of occupational radiation exposures with particular attention to instances in which the investigational levels in Table 1 are exceeded.

The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

TABLE 1
Investigational Levels

	Investigational Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet	1250	3750

Radiation Protection Program

3. Skin of whole body* 750 2250

*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

3. The RSC will perform a quarterly review of fluoroscopy exposure times as presented in the Fluoroscopy Report that is prepared by the RSO prior to the regularly scheduled quarterly RSC meeting. The Fluoroscopy Report is prepared after reviewing patient records and fluoroscopy log books. These log books are kept in all areas of the Hospital that utilize fluoroscopy including Diagnostic Radiology (all R&F systems), the Cystoscopy room in the OR, Endoscopy, the Cardiac Catheterization Lab, Interventional Radiology, and the portable C-Arms.
4. The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.
3. Radiation Safety Officer (RSO)
 - a. Annual and Quarterly Review
 1. Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
 2. Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.
 - b. Education Responsibilities for ALARA Program
 1. The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.
 - c. Cooperative Efforts for Development of ALARA Procedures
 1. Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
 2. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
 - d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
4. Authorized Users
 - a. New Methods of Use Involving Potential Radiation Doses
 1. The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
 2. The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

Radiation Protection Program

- b. **Authorized User's Responsibility to Supervised Individuals**
 1. The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
 2. The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.
5. **Individuals who Receive Occupational Radiation Doses**
 - a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
 - b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
6. **Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses**

This institution hereby establishes investigational levels for occupational external radiation doses which when exceeded will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers. The following actions will be taken at the investigational levels as stated in Table 1:

 - a. Personnel dose less than Investigational Level I. Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.
 - b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II. The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.
 - c. Personnel dose equal to or greater than Investigational Level II. The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any action taken will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.
 - d. Re-establishment of investigation levels to levels above those listed in Table 1. In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.
7. **Signature of Certifying Individuals:** The signatures below are certification that this institution has implemented the ALARA Program set forth above.

Consultant Health Physicist

Radiation Protection Program

1. The Health Physicist (HP) is appointed by contracting through the Hospital. The (HP) advises in the safe use of radioisotopes and is responsible to insure compliance with NRC regulations. The (HP) shall be a non-voting member of the RSC. The (HP) shall report to the RSO. The (HP) is responsible for:
 - a. General surveillance over all activities involving the use of radioactive materials in clinical work.
 - b. Determining compliance with NRC regulations, license conditions, and license renewal.
 - c. Calibrating survey meters.
 - d. Furnishing consultant services on all aspects of radiation protection to personnel and patients.
 - e. Analyzing personnel exposure records periodically and notifying the RSO of exposures approaching maximum permissible doses and recommending appropriate remedial action.
 - f. Conducting training programs and instructing personnel in the safe handling of radioisotopes at periodic intervals.
 - g. Investigating radiation accidents, spills and other unusual occurrences regarding radioactive material.
 - h. Supervising (when possible) decontamination in case of an accident.
 - i. Coordinating licensing applications and amendments with staff and RSO of the Nuclear Medicine Division.
2. Nuclear Medicine (on going services):
 - a. Provides assistance in preparing NRC license application and amendment requests.
 - b. Helps in interpretation of the responsive actions to regulatory procedures.
 - c. Helps with developing the NRC required ALARA program.
 - d. Reviews and coordinates the radiation safety program.
 - e. Provides on site service (if possible) in case of an emergency during working hours, after hours, weekends, and holidays.
3. Quarterly Services:
 - a. Performs radiation protection surveys in Nuclear Medicine to assure compliance with the current NRC license requirements. A written report will be provided.
 - b. Review and analysis of radiation exposure records throughout the hospital and provides appropriate recommendations to reduce exposure to ALARA.
 - c. Review of radiation safety program.
 - d. Inventory and leak tests of all sealed sources of radioactive material. A copy of this report will be provided.
 - e. Calibration and linearity determination of the dose calibrator. A calibration certificate will be provided.
 - f. Calculation of spilled gas clearance times for either aerosols or gas.
4. Annual Services:
 - a. In-service radiation safety education training to hospital personnel.
 - b. Review and coordinate radiation safety program.
 - c. Calibration of survey meters.
 - d. Inspection of all x-ray producing equipment.
 - e. Review of the Quality Management Program and Radiology's Quality Control Program.
 - f. Review all radiation safety policies and nuclear medicine procedure manuals.

November 11, 2008

APPENDIX G
Krueger-Gilbert Health Physics, Inc.
Duties and Responsibilities as Radiation Safety Officer

RSO Duties and Responsibilities: Approximately (8) hours per month conducting radiation protection activities.

The RSO's duties and responsibilities include ensuring radiological safety and compliance with State of Virginia, and DOT regulations, and the conditions of the facilities X-ray Registration & Radioactive Materials Licenses.

The RSO duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily, operation of the licensee's radioactive material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Personnel training is conducted yearly and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to the State of Virginia, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the radiation protection program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.