DEPARTMENT OF THE ARMY
FITZSIMONS ARMY MEDICAL CENTER
AURORA, COLORADO 80045

HSHG-PMH

15 OCT 1985

SUBJECT: NRC License

THRU: Commander
US Army Health Services Command
ATTN: HSCL-P
Ft. Sam Houston, TX 78234-2300

Office of the Surgeon General
ATTN: DASG-PSP-E
6111 Leesburg Pike
Falls Church, VA 22041-3200

TO: United States Nuclear Regulatory Commission
Region IV
ATTN: Mr. Cain
Parkway Central Plaza Building
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

1. The Fitzsimons Army Medical Center (FAMC) renewal application of February 6, 1984 and request to upgrade to a broad scope license inadvertently did not include some of the information previously submitted. However, the following additional information is submitted in response to Mr. Cain's letter of August 22, 1985, (Enclosure 1) Reference Control Number 18398, to allow complete processing of the FAMC application.

2. With regard to FAMC's request to have the Radiation Protection Committee (RPC) approve users, the following is submitted

a. Any physician authorized to use radioisotopes in or on humans does, at a minimum, meet the criteria specified in enclosure 2. The RPC ensures this by requiring the applicant to submit to the RPC for review, completed pages B-4, 6, 7, 8, 9, and 10 of FAMC Reg 40-604, dated 30 July 1983 (Enclosure 3). The RPC members evaluate the submitted documents to ensure that the requester has adequate training and experience in the safe handling of radioisotopes prior to approval of the applicant for the use of radioactive agents in humans.

b. The criteria used by the RPC in approving new users of byproduct material for nonhuman use are as follows:

i. Persons desiring to use radioactive material must complete pages B-1, Request for Authorization to Use Radioactive Material, B-8, Training and Experience Authorized User or Radiation Safety Officer, and pages B-6 and B-7, Radistion Safety Evaluation for Use of Radioactive Material, and forward them to the Health Physics Office for submission to the RPC.

ii. To be approved for non-human use of radioactive material the applicant must document that they have received a college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and have received at least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used. Again, the RPC evaluates the applicant as in Paragraph 2a.

3. FAMC has no intended use for the requested 5 curies of krypton-85 nor 1.5 curies of cesium-137 in other than sealed sources; therefore, the request for 5 curies of krypton-85 and for 1.5 curies of cesium-137 in other than sealed form is deleted.

4. The qualifications for CPT Dunston as Radiation Protection Officer are provided in Enclosure 4 as a completed 313(M) Supplement A, a Curriculum Vitae, and a copy of his M.S. diploma.

5. Information concerning use of xenon-133 is provided as Enclosure 5. Information concerning use of krypton-85 is not provided because FAMC has no intended use for the requested 5 curies of krypton-85 and the request for 5 curies of krypton-85 is deleted.

6. New floor plans for all use areas showing adjacent areas, shielding, and waste areas and contents are submitted (Enclosure 6).

7. The various paths intended for waste disposal are submitted on Appendix J of the regulatory guide 10.8 (Enclosure 7).

8. The FAMC program for maintaining radiation exposures ALARA consists of implementation on 23 October 1980 of the model ALARA program proposed by the NRC letter dated 16 July 1980 with a simple redefinition of terms (at FAMC, Radiation Safety Committee equals the Radiation Protection Committee and Radiation Safety Officer equals the Radiation Protection Officer). To maintain exposures ALARA all radiation protection instruction emphasises the requirement of all personnel to be alert for ways to minimize exposures and managements' commitment to keeping exposure ALARA. In addition, any potential exposure situation is evaluated to ensure that the radiation protection principles of minimizing time of exposure, of keeping as much distance as practicable between the source of exposure and the individual, and of using fixed or portable shielding to reduce the exposure rates are enforced. FAMC will adopt Appexdix O of the Regulatory Guide 10.8 (Enclosure 8).

9. The procedures used for calibration of dose calibrators are as prescribed in Appendix D Section 2, Methods for Calibration of Dose Calibrator. FAMC will adopt Appendix D, Section 2, of Regulatory Guide 10.8 for calibration of FAMC dose calibrators. With the exception that under Item E, test of instrument linearity, FAMC performs the test using a vial or syringe of Tc-99 whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmacential kit, typically 250 mCi. FAMC uses a Cs-137, Co-57, and Ba-133 sources whose activity levels approximate those levels normally encountered in

clinical use. These are NBS traceable and relatively long lived sources. The Ba-133 sources is only used for accuracy tests (Enclosure 9).

10. Appendix L of FAMC Reg. 40-604 has been updated to account for changes in DOT regulations in Title 49. A copy of the updated Appendix L of FAMC Reg. 40-604 is provided as enclosure 10 and replaces the Appendix L of FAMC Reg. 40-604 in our 6 February 1984 application.

11. Instrumentation used for leak test sample analysis and other wipe test analysis consists of a two channel liquid scintillation counter, a two channel auto gamma counter, and a well counter with a sodium iodide thallium activated crystal. Specific instrumentation currently possessed and used by FAMC for leak test sample analysis and other wipe test analysis, detection limits, and associated reference standards are submitted (Enclosure 11).

12. The personnel training program at FAMC consists of the following:

a. All newly arrived personnel at FAMC receive a 15 minute lecture at the Command required newcomer's orientation. A representative of the radiation protection staff tells where radioactive materials and sources of ionizing radiation are used or stored, shows a radioactive material and radiation area sign and explains that they indicate an area where people should stay out of except on official business cleared by a member of the hospital staff, the committment of management to the ALARA principal and what ALARA is.

b. Radiation workers are properly instructed before assuming duties with, or in the vicinity of radiation sources by requiring them to read FAMC Reg. 40-604 Appendix E, F, & G, NRC Guide 8.13, NRC Guide 8.29, and AR 40-14, Control and Recording Procedures for Occupational Exposure to Ionizing Radiation. In addition, they receive periodic training at least every 12 months or as required by significant changed in their work or in the license.

c. Ancillary personnel (e.g. nursing, housekeeping, clerical) whose duties require them to work in the vicinity of radiation sources are informed about radiation hazards and appropriate precautions on an annual basis or as needed (e.g. nursing staff handling a radiotherapy case).

d. Training for radiation workers is provided during annual refresher training and whenever there is a significant change in duties, regulations, or the terms of the license.

e. Instruction as required by 10CFR Part 19 in lecture form includes: 1) Those terms of the license pertinent to radiation safety; 2) Areas where radiation sources are used or stored; 3) Potential hazards associated with radiation exposure; 4) Radiological safety procedures appropriate to their respective duties; 5) Pertinent NRC regulations; 6) Rules and regulations of the license; 7) Obligation to report unsafe conditions to the radiation protection officer; 8) Appropriate response to emergencies or unsafe conditions; 9) Right to be informed of their radiation exposure and bioassay results and; 10) that FAMC has on file in the Radiation Protection Office notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence).

f. Orientation procedures for new personnel assigned to Nuclear Medicine Service or Radiation Oncology (Radiation Therapy) Service are submitted (Enclosure 12).

13. The bioassay procedures for radioactive iodine consists of a thyroid uptake measurement performed in Nuclear Medicine Service. Currently, personnel who handle millicurie amounts (>1mCi) of I-131, I-123, or I-125 receive a 24 hr. thyroid uptake measurement (for Nuclear Medicine personnel) or a thyroid uptake measurement within 72 hours of exposure for all other personnel. In addition, in the first month of each quarter every individual assigned to the Nuclear Medicine Service has a neck count taken. Action levels and other guidelines enforced at FAMC are those in NRC Regulatory Guide 8.20. Bioassay procedures for tritium are described in the enclosed instructions (Enclosure 13).

14. In addition to the minimum rules of laboratory safety for radiation workers listed on pages C-3 and C-4 of FAMC Regulation 40-604 (Tab V of FAMC application dated 6 February 1984) the following special safety instructions are provided to individuals using phosphorus-32:

a. Use low density shielding in order to keep Bremstrahburg radiation at a minimum.

b. Perform a mandatory radiation survey and wipe test procedure after each use.

c. Wear a TLD ring badge whenever a procedure involves 1 mCi or more.

d. Use a dry run not involving radioactive material prior to performance of unfamiliar procedures in order to preclude nonexpected complications. The Radiation Protection Officer should be present during new procedures.

e. Use eye protection for procedures that involve 10 mCi or more.

f. In addition, these special safety measures for use of P-32 have been individualized through Departmental Standard Operating Procedures (Enclosure 14).

15. The procedures and precautions for use of radioactive material in animals at FAMC are as follows:

a. The use of radioactive material in animals at FAMC is currently done in the Department of Clinical Investigation (DCI). Currently, DCI has an American Association of Laboratory Animal Care approved facility. This facility has the capability and is approved to maintain and conduct biomedical research on many

species of animals to include swine, sheep, sub-human primates, dogs, cats and a multitude of rodents. As such, the facilities already meet many physical standards which would be required for the use of radioisotopes. Examples include but are not limited to such equipment and facilities as metabolic and/or other non-porous species specific cages, non-porous walls, ceilings and floors, approved air exchange rates, temperature and humidity control.

b. Protocols using radioactive materials in animals must be approved by both the Animal Use Committee and the Radiation Protection Committee. Favorable review by these committees is contingent upon the investigator submitting, in the protocol, detailed plans of the procedures and precautions which the principal user will assure will be taken to safeguard users, animal-care technicians and of course the environment. This type of review would specifically consider variables such as species of animal, radionuclide, activity level, carrier, tissue or organ of radionuclide deposition and levels of excretion. From these variables the principal user is able to describe protocol specific procedures detailing precautions. These precautions would result in specific instructions prepared by the principal user regarding (1) the handling of animals, animal waste, and carcasses; (2) the cleaning and decontaminating of animal cages and (3) procedures restricting access to the room. This results in maintaining exposures ALARA on a specific basis. Restriction include both locks and posting.

c. Procedures to be followed would include the following:

1. Excreta, contaminated bedding, or animal's bodies (sacrificed or living) containing radioactive materials, whose half-life is less than 30 days, are retained by the user for radioactive decay prior to disposal.

Excreta, contaminated bedding, or sacrificed animals may be conveniently held by wrapping in plastic (polyethylene) bags and freezing; by placing the material in a

chemical preservative; by autoclaving or by fixing in concrete or plaster. Animals not sacrificed may be retained for later use provided excreta continues to be collected for a sufficient time to assure that the amounts appearing in the excreta are no longer significant.

In the case of short-lived animal wastes (half-life less-than 30 days), the waste is held for at least 10 half-life periods and then monitored to determine if it can be nonradioactive waste. However, under no circumstance may such wastes be permitted to be used directly or indirectly in the human food chain (for example, an experimental cow to which a radionuclide has been administered may not later be used as a source of milk for human consumption or as a source of fertilizer for crops intended for human consumption).

2. Excreta, contaminated bedding, or animals containing radioactive materials whose half-life is greater than 30 days should be prepared as above (C-1 Second Paragraph).

Excreta, contaminated bedding, and sacrificed animals are later processed by the Radiation Safety Office staff for land burial. Animals not sacrificed may be retained for other uses provided that excreta are collected for a sufficient time to assure that significant levels of activity are no longer being eliminated, and that the animals of their excreta are not later used directly or indirectly in the human food chain.

d. Instructions for cleaning and decontaminating animal cages are as follows:

1. Facilities occupied by animals containing administered radioactive materials are surveyed at the end of each experimental protocol, to include swipe testing for removable contamination.

2. If removable contamination is found, the radioisotope user decontaminates the area, and the area is checked again with swipe tests.

3. The RPO is provided with copies of all swipe test results, to include ones which are initially negative for contamination.

e. Experimental animals containing administered radioactive materials are retained in controlled radioisotope use area and are therefore at all times after dose administration either:

1. Under the direct administrative control of the radioisotope user, or

2. In a restricted access area with doors locked.

16. As a consequence of increases to FAMC medical mission, we desire to increase our possession limit of cesium-137 as sealed sources. We propose to buy from 3M 4 sealed sources of Cs-137, Model 6504, 63 mCi each and 2 sealed sources of Cs-137, Model 6505, 76 mCi each. To accomodate these sources, FAMC needs to increase our possession limit to 1.5 curius of Cs-137 sealed sources to be used for brachytherapy purposes. These new sources will be stored in Radiation Therapy, Building 500 and used in accordance with the procedures in effect for using our current brachytherapy sources.

17. For further information please contact CPT(P) Dunston at (c) (303)361-4289 or LTC Williams at (c) (303)361-8801.

Paul L. Shetler

PAUL L. SHETLER
Colonel, MC
Acting Commander