OCT 0 4 1996

James L. Spigarelli
Senior Vice President
Director of Kansas City Operations
Midwest Research Institute
425 Volker Blvd.
Kansas City, MO 64110-2299

30-5083

Dear Mr. Spigarelli:

This is a corrected copy of the letter dated October 1, 1996, that transmitted Amendment No. 45 to NRC License No. 24-02564-02 to you. Item B.1.a., page 4 paragraph 4, second sentence, should have referred to "item j." instead of "item ???" We apologize for any confusion or inconvenience this way have caused you.

Enclosed is Amendment No. 45 to your NRC Material License No. 24-02564-02 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9387 so that we can provide appropriate corrections and answers.

A. 1. Please note that, at this time, we changed the expiration date in item no. 4 of your license to reflect the one-time extension of your license, in accordance with 10 CFR 30.36(a)(2), copy enclosed. You should have received additional correspondence from us concerning this regulation and its effects on your license.

2. In preparing this amendment, we took the opportunity to update and reformat your license as discussed below. These changes were essentially administrative modifications only that should have no effect on your licensed program.

a. We deleted Condition No. 20., as it appeared on Amendment No. 44, because the regulations in 10 CFR 30.35(g) contain the same provision. Therefore, this Condition is no longer necessary.

b. We deleted Condition No. 16. as it appeared on Amendment No. 44, because the regulations in 10 CFR 20.1901(b) contain the same provision. Therefore, this Condition is no longer necessary.

c. We corrected Condition No. 10.B. to authorize the use of the sources in Subitem 6.M. in gas chromatography devices used at temporary

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job sites. This Condition incorrectly referred to "Subitem 6.F." on Amendment Nos. 42, 43 and 44. We apologize for this error and any inconvenience it may have caused.

3. We noted that your application dated June 4, 1996, and your letter dated June 5, 1996, were signed by James McHugh. Please be reminded that all future correspondence to us must be signed by a senior management official. In the alternative, a senior management official may designate an authorized signatory to us, in writing, such as the Radiation Safety Officer or a mid-level management representative.

B. Please note that, at this time, we were unable to authorize the licensed program changes referred to in items 9., 10. and 11. of your letter dated June 5, 1996, because the information submitted in this letter was insufficient for us to complete our review. If you wish to pursue these authorizations, please address the information requested below and submit it to us as additional information to Control No. 301401. We will then continue our review, without an additional fee, limited to these authorizations. Be advised that, if you request anything other than these authorizations, an amendment fee will be required.

Please address the following:

1. This refers to the telephone conversation on September 19, 1996, between Colleen C. Casey and James McHugh concerning your request to incorporate your revised Radiation Safety Manual (RSM) into the license.

   Ms. Casey explained the consequences of such an amendment, especially since your RSM, as submitted, contained numerous sections that extend beyond NRC's regulatory authority, such as chemical and fire hazards, medical emergencies/evacuations, etc. These areas, among others, did not pertain to byproduct material use.

   Ms. Casey suggested that, if significant changes have been made to your licensed program and if you want these changes incorporated into the license, it may be best to reconsider using the RSM to achieve this.

   The RSM should be a dynamic, "living" document, subject to change as often as each licensee deems necessary. It should also be **based upon the statements, representations and procedures contained in the license, especially in your correspondence, found in the "tie-down condition," number 19.**

   The documents in the "tie-down condition" form much of the framework of the licensed program and describe, in sufficient detail to evaluate safety, the basic components and procedures, facilities and equipment, and training and

experience of personnel to adequately support the proposed possession, use, storage and disposal of licensed radioactive material.

The actual, detailed "step-by-step" radiation safety program procedures engaged in by licensed personnel expand upon the licensed documents and constitute the RSM. The RSM for each institution may or may not also contain procedures, provisions and safety precautions for non-NRC licensed activities.

Due to the highly prescriptive, specific nature of the information contained in the RSM, it is usually best to **not** include it in the "tie-down condition." It may be submitted if a license reviewer requests it or as a **reference document only.** In the latter case, the licensee should clearly state that the RSM is not to be included or "tied-down" in the license itself.

Mr. McHugh indicated agreement with the licensing philosophy for RSM's above and wants to reconsider this portion of the original amendment request. Therefore, we are returning both copies of the revised RSM to you at this time, pending the outcome of your final decision in this matter.

In addition, we are enclosing several regulatory guides, copies of current regulations and general, supplemental guidance to assist you in preparing a "non-RSM based" license amendment.

Please note that the supplemental guidance presented below may not entirely pertain to your licensed program. As Ms. Casey discussed with Mr. McHugh, we are including it only because experience has shown us that it may have some value in preventing deficiencies that commonly occur when licensees modify their licensed programs in entirety, as it appears you are interested in doing.

a. Authorized Users

In order for us to approve your future authorized user applicants, it will be necessary for you to demonstrate that each applicant's training and experience adequately support his/her proposed use of byproduct material, with respect to the types of radionuclides and quantities to be used and specific procedures/protocols to be followed.

For example, a minimal level of training and experience would be necessary for an authorized user working with microcurie amounts of pre-labelled soft beta emitting radionuclides "in vitro."

Additional training and experience in the safe handling of radioactive materials, appropriate to the type of use, would be necessary for an authorized user working with millicurie amounts of gamma-emitting microspheres "in vivo" or for an authorized user working with millicurie or curie amounts of tritium, iodine-125, carbon-14 or phosphorus-32 in labelling procedures.

Please refer to sections 16 and 17 of the enclosed Regulatory Guide 10.7, enclosed, for guidance in preparing your response. Also, the criteria in 10 CFR 33.15(b), enclosed, may assist you. **Generally, please do not submit resumes or curricula vitae- use the enclosed Supplement A forms only and, if appropriate, include a brief narrative statement of explanation on a separate sheet of paper.**

Specifically, each future applicant will need to submit additional information, as follows:

Please demonstrate that the applicant's training and experience are commensurate with his proposed possession and use. Please specify which radionuclides and the maximum quantities of each radionuclide that the applicant wishes to be authorized for (should be part of each radionuclide's total possession limit on the license), including waste activity.

Describe in **simple** terms the types of work that the applicant wishes to perform, such as labelling compounds with volatile forms of tritium, use of pre-bound materials "in vitro," etc.

Please state whether the applicant intends to conduct "in vivo" research studies with animals. If so, please respond to the information requested in item j below.

Please describe in detail each applicant's on-the-job and formal coursework training, including the location and duration of the training and the dates when the training was received.

Training should consist of at least forty hours and cover:

(1) principles and practices of radiation protection,

(2) radioactivity measurements, standardization, and monitoring techniques,

(3) mathematics and calculations basic to the use and measurement of radioactivity,

(4) biological hazards of exposure to radiation appropriate to the type and form of byproduct material to be used, and

(5) radiation detection instrumentation.

Address each applicant's training in each of these areas on the enclosed Supplement A form, "Training and Experience." The description of prior use of licensed materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained (and the facility's license number), the dates and duration of experience, the names of previous authorized users/principal investigators that the applicant worked under and the types of use.

Please prepare the requested information separately for each different facility that the applicant studied/worked at, i.e., the information for training/experience at "XYZ University" should be complete and distinct from training/experience at any other academic institution, etc.

b. Management Oversight

10 CFR 20.1101(c) requires that each licensee review the radiation protection program content and implementation at least annually. Submit a description of your program for performing the required annual review. It should include the following criteria:

(1) Senior management oversight of the radiation protection program. Specify the mechanisms that will be used by senior management to ensure that they are aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program.

(2) Review of the Radiation Safety Officer and staff performance. Specify the minimum qualifications for an individual who will perform this review, and confirm that the results will be reported to senior management.

(3) Audits by the Radiation Safety Officer to determine user compliance with the requirements of the NRC license and your radiation protection program. Audits should include such topics as: reviews of users' inventory and survey records,

evaluation of users' radiation safety procedures through observation and discussion, performance of independent work area surveys, security of licensed material and appropriate implementation of posting and labelling requirements.

(4) Please confirm that records of audits will be maintained and specify what actions will be taken when problems are identified by the auditor(s).

c. Licensed Material Inventory and Security

(1) Please describe your procedures for maintaining a continuous, running inventory for all licensed materials, sealed and unsealed, including materials in storage, in waste streams and material being held for "decay-in-storage." Your inventory and control system should have the capability to assure that licensed material possession limits are not exceeded and that material is accountable throughout the institution at any given time.

(2) 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.

Describe how you will preclude the unauthorized removal of licensed material from the place of storage and in unrestricted areas.

Please note that common areas, rooms, hallways and corridors that contain equipment used to store radioactive materials are not considered secure unless they are locked or directly attended by appropriately trained staff.

(3) Submit your procedures for transfer and transportation of licensed material between authorized users at your facility. Confirm that all such transfers, including transfers of material to and from other licensees, will be coordinated through the Radiation Safety Office.

Describe your program to control such transfers, including updating of your materials inventory and performing audits of users' procedures. Confirm that your authorized users will be adequately trained in these procedures to prevent unauthorized

transfers of licensed material between individuals at your facility and to and from other licensees.

d. Radioactive Package Receipt and Opening Procedures

(1) Describe your procedures to ensure that all procurement of licensed material and all uses of licensed material are properly authorized by the license and approved by your Radiation Safety Officer.

(2) Please clarify how radioactive materials packages are logistically received and delivered at your institution, especially packages received after normal duty hours. Please describe which departments are responsible for the receipt of radioactive materials packages throughout a 24-hour day/weekends and how packages are delivered to the appropriate recipient.

Is there a central receiving point for surveys and check-in that the RSO has control over and from which packages are delivered to or picked up by the appropriate end user? If not, explain how you ensure the security of packages awaiting delivery/pick up and that individuals performing surveys, etc. are appropriately trained to do so and respond to emergencies, such as unusual radiation levels, unusual quantities of removable contamination, spills, etc.

(3) If you are considering having radioactive materials packages delivered directly to the end user upon receipt, please be advised that this practice risks your accepting receipt of materials that you may not be licensed for or materials in greater activities or different forms than you are authorized for. Such incidents have been reported to NRC by other institutions and should be considered. Please evaluate these procedures carefully and advise us if you change them.

e. Training Program

(1) Describe your program for training and refresher training in detail for all persons who handle licensed material or who frequent areas where licensed material is used. This training program must include sections that are tailored to various types of radiation and ancillary workers, appropriate to your

program, such as authorized users, laboratory supervisors and technicians; waste compactor operators, the purchasing department, personnel receiving licensed material; housekeeping, nursing, security, and other ancillary personnel; and the radiation safety office staff.

We have enclosed a copy of Regulatory Guide 10.8, Rev. 2, which is normally used for our human use/medical licensees. However, a number of the model procedures and certain exhibits contained in this guide have generic applications and many of our non-medical licensees have found this guide useful.

Regulatory Guide 10.5, "Standard Review Plan For Applications For Licenses of Broad Scope," Appendix I, also has a model training program that may be of assistance in formulating your response. (Note that we reference Regulatory Guide 10.5 only because experience has shown that certain sections of this guide may be successfully used by non-broad scope licensees.)

You may also wish to refer to the enclosed copy of Regulatory Guide 10.7, Item 15.D., for assistance, as well as 10 CFR Part 19.12, enclosed.

(2) Please refer to Appendix A, Regulatory Guide 10.8, Rev. 2, and confirm that your training program for radiation workers (authorized users, technicians, assistants, etc.) as well as ancillary staff will be conducted in accordance with these model procedures.

(3) Please confirm that orientation and refresher training will be provided for all persons who handle licensed material or who frequent areas where licensed material is used, in accordance with revised 10 CFR Part 19.12, enclosed. This training program should include a review of emergency procedures and response criteria and include sections that are tailored to various types of radiation and ancillary workers such as authorized users, laboratory supervisors and technicians; personnel receiving licensed material; housekeeping, security, and other ancillary personnel.

(4) Please provide the names and a brief summary of the training and experience qualifications of the individuals providing formal training. Please do not send resumes or curricula vitae.

(5) Please confirm that, for all workers and authorized users, annual refresher training will include components that will serve to maintain an awareness of radiation safety with respect to the changes in the license, changes in regulatory requirements, and "lessons learned" experiences derived from NRC Information Notices, NRC's NMSS Newsletters and NRC inspection findings at your own institution.

(6) Please confirm that authorized user investigators will provide training to their laboratory staff, such as "laboratory-specific" radiation safety procedures and techniques for using licensed material.

(7) Please confirm that records will be maintained of all radiation safety training activities, to include the dates of training, the topics covered, the approximate amount of time spent on each topic, the names of instructors, a written assessment or test for each "student" documenting satisfactory mastery of the subject matter, the location (if appropriate) and materials involved in the training provided and the names of attendees.

f. Reporting of Incidents

Please update your procedures and confirm that the reporting requirements in 10 CFR 21 (enclosed), 10 CFR 20.2201- 20.2206 and 10 CFR 30.50, enclosed, are followed.

g. Internal Exposure Controls

(1) Please confirm that, when taking bioassay measurements for individuals using radioiodines, you will employ appropriate crystal detectors, including low and high energy scintillation probes to achieve greater efficiency.

(2) Please also describe your procedures to ensure that geometrical variations in the placement of the detector probe in relation to the thyroid gland will be minimized and accounted for.

(3) Please confirm that you will use a scaler or multi-channel analyzer, with adjustable discriminator settings, to ensure that reference standard, background and bioassay measurements are taken at the appropriate energy level for the radionuclide of interest. For example, a survey instrument with a GM probe is usually unable to achieve such sensitivity.

(4) Please note that bioassay regulatory requirements and guidance are not limited to hydrogen-3, iodine-125 and iodine-131. Please review the enclosed copy of Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions For A Bioassay Program," and 10 CFR 20.1204, 20.1502 and 20.1703 to determine whether bioassay procedures for other authorized radionuclides should be developed and incorporated into your licensed program.

Please prepare additional procedures for our review, if appropriate, or indicate why they may not be necessary. Specify the action limits for bioassay and external (skin, etc.) contamination surveys and the actions to be taken when these limits are exceeded. The action limits should be in appropriate units.

Please also specify whether baseline bioassay measurements for workers will be conducted for the use of radionuclides other than hydrogen-3, such as carbon-14 and the radioiodines, among others.

(5) Describe the laboratory equipment used when working with volatile radioactive materials, such as iodine-125. Confirm that a fume hood will be used and specify if a filter will be used. Specify the minimal face velocity on the fume hood and the frequency at which the face velocity will be measured.

(6) Please specify the criteria used to set the type and frequency at which routine surveys for airborne licensed materials are performed, if appropriate (e.g., breathing zone and general work area air sampling, hood and room ventilation air flow rate measurement, and stack effluent sampling).

Describe the instrumentation that will be used for sample collection and analysis, the calibration method and frequency for each, and specify the lower limit of detection and action levels for each. Please identify the individuals who will be performing these air sampling tasks, if someone other than the RSO will do them, i.e., a consultant or contractor.

If you will not survey for airborne licensed materials, please justify and explain your position and advise us of the maximum quantities of volatile radioactive materials that will be used or opened by your researchers at any one time.

h. Area Radiation Surveys

(1) Please explain/clarify your description of the routine survey program, including the specific types of laboratory areas to be surveyed, the types and levels of radiation and contamination considered to be acceptable, and provisions for maintaining records of surveys. Please provide examples of the types of radionuclides, activities and protocols/techniques that will illustrate your survey frequencies.

(2) The individual user should supplement the surveys performed by the radiation safety staff. Regularly used laboratories should be surveyed for contamination at the end of each workday (except when quantities less than those in Appendix C to 10 CFR Part 20 are handled by an employee at any one time), and the user should maintain records of each survey in units required by 10 CFR Part 20, even if only a single measurement is necessary.

i. Survey Instruments and Calibrations

For your research laboratories, if survey instruments measure "counts per minute (cpm)" only, an electronic alignment may suffice. However, even for these instruments, it would be well to indicate radiation field measurements (at least one) that correspond to a "cpm" measurement, using a check source. It is preferable to use a check source whose radiation type and energy is similar to a radionuclide commonly used in that laboratory.

For instruments that measure "cpm" as well as radiation fields in "milliroentgen per hour" or similar units, calibration in an actual radiation field may be most appropriate.

Please re-evaluate your calibration procedures and advise us if you will implement a revised calibration procedure, in accordance with these considerations.

j. Animal Use

Your license indicates that you will use radioactive materials in animal studies. Please address completely the information requested below:

(1) Please identify the laboratories (building and room numbers) where animal studies will be performed and where the animals will be housed.

(2) Please describe the types of cages (metabolic or open-air, etc.) and housing you will provide for the animals, how they will be maintained in a sanitary condition and by whom. Explain whether the animals will be used in the authorized users' laboratories, in a separate animal care facility or both. Please submit diagrams, not blueprints, of all facilities where animals will be used.

(3) Please identify the individuals, by position, who will care for the animals and describe their duties, radiation safety training (topics and frequency) and supervision. Please submit a copy of the instructions that will be provided to the animal caregivers and authorized users, including emergency procedures, safe handling procedures and radioactive animal security procedures.

(4) Describe in greater detail how the animals and their associated wastes will be disposed of. Will the animals be sacrificed and, if so, how will the carcasses be disposed of? How will contaminated holding pens or cages be cleaned? How will contaminated litter or biological fluid/tissue samples be disposed of?

(5) Which types of animals do you anticipate using for these "in vivo" studies and please give examples, i.e., rabbits, mice, rats, etc.

k. Waste Management

(1) Please review Item 11 in Regulatory Guide 10.5 and Item 14 in Regulatory Guide 10.7 and provide us with a detailed description of your disposal methods.

(2) Please confirm that you will not store radioactive wastes with other hazardous wastes, such as flammables, explosives, caustics and biohazards.

(3) Please note that if one of your waste disposal methods will be releases to the environment through the sanitary sewer or by evaporative release, you must submit at least one set of sample calculations illustrating that your "worst case" and/or "typical" disposals of aqueous waste to the sanitary sewer would not exceed the limits in 10 CFR 20.2003 and Table 3 of Appendix B to Part 20.

Please be reminded that some of the values in Table 3, Appendix B to Part 20, have changed and are lower than they were in "old" Part 20. Please submit at least one set of similar calculations for your "worst case" evaporative release scenario.

(4) Describe any significant radioactive waste treatment procedures at your facility, such as evaporation, solidification, liquid scintillation vial crushing, etcetera, as appropriate. Include the following in your description:

(a) Treatment method and the type, quantities, and concentrations of waste to be treated.

(b) Special equipment needed including a description of the type, manufacturer and model, and capacity, such as fume hoods, "hot sinks," etc.

(c) Analysis of the potential for airborne release of licensed material.

(d) Equipment location within your waste processing area(s) and a ventilation and filtration system description, including your procedure for monitoring filter blockage and exchange.

(e) Methods used to monitor releases to unrestricted areas, and internal and external monitoring of workers.

(f) Survey types and frequencies performed for contamination control.

(g) Instructions provided to equipment operators including instructions for protective clothing, checks for proper functioning of equipment, uncompacted waste handling methods and examinations performed for container defects.

(5) Recently, the licensed radioactive waste disposal site located in Barnwell, South Carolina, reopened and is accepting most forms of low level waste (LLW) again.

IN 90-09, copy enclosed, states, in part, that "LLW should be stored only when disposal capacity is unavailable" . . . and "waste should not be placed in contingency storage if the ability to dispose of waste at a licensed disposal site exists."

Please note that it is expected that you will dispose of LLW by shipment to the Barnwell, South Carolina site, in lieu of electing to utilize extended interim storage of LLW. If you advise us that you will not ship LLW to Barnwell, it will be expected that you demonstrate that Barnwell will not accept your waste.

(6) Should you request to dispose of licensed material with half-lives less than 120 days by decay-in-storage, please submit the following information:

(a) Please submit a diagram of the area where the waste will be decayed-in-storage. Show the type, location, and thickness of shielding that you will have available in this area on your diagram.

Identify adjacent unrestricted areas located across the walls from the storage area and show that adequate steps have been taken to assure that radiation levels do not exceed the limits specified in 10 CFR 20.1301 (enclosed).

(b) Describe your security measures for the decay-in-storage area.

(c) Confirm that radiation and removable contamination surveys in this area will be performed and recorded at least weekly.

(d) Describe your procedures for monitoring the waste to assure that it has decayed to background levels prior to disposal. At a minimum, your description should include these points:

(i) Monitor the waste in a low background area.

(ii) Monitor with a low level GM type survey meter as appropriate for contamination surveys. Use the most sensitive scale.

(iii) Remove all shielding prior to monitoring.

(iv) Maintain records of these surveys as required under 10 CFR 20.

C. Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of

NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,
Original Signed By
Colleen C. Casey
Nuclear Materials Licensing Branch

License No.: 24-02564-02
Docket No.: 030-05083

Enclosures:
1. 10 CFR Part 19
2. 10 CFR Part 20
3. 10 CFR Part 21
4. 10 CFR Part 30
5. 10 CFR Part 40
6. 10 CFR Part 70
7. 10 CFR Part 71
8. Reg. Guide 10.5, Rev. 3
9. Reg. Guide 10.8, Rev. 2
10. Reg. Guide 8.20
11. Reg. Guide 8.9
12. Reg. Guide 10.7
13. IN 94-07
14. IN 90-09
15. Amendment No. 45

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