The University of Michigan

OCCUPATIONAL SAFETY AND ENVIRONMENTAL HEALTH
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KENNETH C. SCHATZLE
Director

August 1, 1990

William Adam, Ph.D.
Nuclear Materials Licensing
U.S. Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60337

RE: Additional Clarification for Renewal of NRC License No. 21-00215-04 [Control No. 85527]

Dear Dr. Adam:

Per your correspondence dated June 27, 1990, please find below responses to the items for which additional clarification was requested.

1.0 ITEM 1.0 - BIOQUANT, INC. ADMINISTRATIVE, PROCEDURAL & PHYSICAL CONTROLS

During the July 28, 1987 quarterly meeting, The University of Michigan - Radiation Policy Committee (RPC) approved with specific conditions commercial activity in University facilities by non-University personnel. Specifically, the approval was made with the following conditions:

1.1 The use of radioactive material at The University of Michigan (U-M) is subject to Radiation Policy Committee (RPC) review, authorization, and regulation. The RPC affirms that it requires access to information for all uses of radiation and radioactive material at facilities whether or not the facility staff members are U-M employees. The policy also applies to proprietary information.

1.2 Independent Nuclear Regulatory Commission (NRC) licenses are not permitted. Research and work with byproduct material is subject to Radiation Safety Service (RSS) control under The U-M Broad Scope/Byproduct Material License (21-00215-04). The Byproduct Material License requires the review and approval of all applications for the possession, use and transfer of radioactive materials and radiation.

Bioquant, Inc. of Ann Arbor, Michigan is a biotechnology firm spun off from the U-M and is located in a U-M supported building (Auxiliary Services Building) at 1919 Green Road. As noted above, Bioquant is authorized to receive, possess, and use radioactive materials under the U-M Broad Scope/Byproduct Material License (21-00215-04) as approved by the Radiation Policy Committee. All guidelines, protocols, and regulations for the safe use of radioactive material and the manufacturing of diagnostic RIA kits at Bioquant are permitted under the supervision of Radiation Safety Service. Radiation Safety Service has specific control over the following Bioquant activities involving radioactive materials:

1.3 Application Authorization & Approval Process

1.4 Radiological Safety Training

1.5 Radioactive Waste Disposal

1.6 Radiation & Radioactive Contamination Monitoring and Survey Progress

1.7 Iodination Safety Procedures

1.8 Personnel Dosimetry & Exposure Records

1.9 ALARA Procedures

1.10 Airborne Radioactivity Exhaust Monitoring

1.11 Radioactive Material Receipt for and Transfer to Bioquant

1.12 Instrument Calibrations

1.13 Other General Radiological Control & Regulatory Compliance Protocols

The U-M is not responsible for the distribution license authorized by and issued to Bioquant, Inc. by the NRC for purposes of distributing diagnostic (RIA) kits. Although Radiation Safety Service receives and records in-coming radioactive material packages, Bioquant is responsible for ordering and payment of radioactive material to be used at Bioquant.

While there is a distinct separation of the day-to-day administrative, procedural, and physical controls of licensed activities between the U-M and Bioquant, Inc., Radiation Safety Service is responsible for ensuring radiation safety & regulatory compliance issues at Bioquant, Inc.

2.0 ITEM 2.0 - USER-CONDUCTED SURVEY PROGRAMS

Please note below the revision to Item 2.0 clarifying the contamination control program to be implemented at The University of Michigan:

2.1 "Authorized Users of radioactive material are responsible for evaluating the contamination status of each laboratory under their authorization. Users are instructed to monitor their laboratories for radioactive contamination using appropriate survey instruments or conducting wipe/smear tests in suspected areas. The frequency (weekly or monthly) of radiological surveys to be conducted by users will be determined by the Radiation Safety Service health physics staff based on the individual isotopic activity limit specified in the ORDER/TRANSFER LIMIT section of each Authorized User's authorization application.

Authorized Users who have an individual isotopic order/transfer limit of greater than 10 millicuries of unsealed (liquid or powder) radioactive material will be required to perform contamination surveys on at least a weekly basis. Users who have individual isotopic order/transfer limits equal to or less than 10 millicuries of unsealed radioactive material will be required to perform contamination surveys at least monthly.

Note that the frequency of user-required contamination surveys may be revised at the discretion of the Radiation Safety Officer or Radiation Policy Committee based upon an evaluation the departmental semi-annual isotopic inventory.

The adequacy of Authorized User contamination control programs will be audited routinely by Radiation Safety Service personnel. The audits will include surveying each laboratory actively using unsealed radioactive material. Audit surveys are conducted at least once per quarter by Radiation Safety Service .

Laboratories using sealed or plated radioactive sources are evaluated by Radiation Safety Service at intervals prescribed for routine leak-testing of sealed/plated sources. Sealed/plated sources are leak-tested and inventoried at regular intervals as noted in Item 10, page 7, Section F."

3.0 ITEM 5 - RADIATION SAFETY OFFICER AUTHORITY

Please note below the revision to the second paragraph of Item 5.0 clarifying the authority delegated to the Radiation Safety Officer (RSO) by the Radiation Policy Committee (RPC). The entire second paragraph should read:

"Minor deficiencies noted during an audit will be brought to the attention of the Authorized User for in-house corrective action. Radiological deficiencies noted as being a threat to the health and safety of personnel will be brought to the attention of the Radiation Safety Officer (RSO). The RSO has the authority to halt immediately any actions involving radioactive material or radiation which 1) poses a threat to personnel, the environment, or facility safety, or 2) constitutes a violation of the conditions of regulatory agency regulations or conditions of The University of MIchigan license. Deficiencies deemed significant by the RSO will be reported to the RPC."

4.0 ITEM 5 - CORRECTIVE ACTION FOR REPETITIVE DEFICIENCIES

Please note below the revision to the third paragraph of Item 5.0 clarifying the degree of corrective action which will be implemented by the Radiation Policy Committee or Radiation Safety Officer for repetitive deficiencies:

"Repetitive deficiencies of non-compliance will be evaluated on a case-by-case basis, documented, and reported to the Radiation Safety Officer (RSO) and Radiation Policy Committee (RPC). The Authorized User will be notified of the repetitive non-compliance item(s) and any corrective action(s) warranted by the RSO or RPC to ensure personnel, environmental, and facility safety and regulatory compliance.

Remedial action for serious or repetitive violations may include, but are not limited to, the following:

4.1 Temporary suspension of authorized activities,

4.2 Requirements for addition training,

4.3 Modification of facilities or procedures, and/or

4.4 Revocation of authorization to use radioactive materials.

The RSO has the authority to 1) temporarily suspend authorized activities, 2) require additional training, and 3) require facility or procedural modifications; however, only the RPC has the authority to revoke an Authorized User's authorization to use radioactive material."

5.0 ITEM 5 - TRAINING & EXPERIENCE REQUIREMENTS FOR RADIOLOGICAL SAFETY AUDITORS

Please note below the additional information regarding the training and experience requirements for departmental radiological safety auditors:

"Individuals responsible for conducting radiological safety audits at The University of Michigan will be trained and instructed by a Radiation Safety Service health physicist and/or the Radiation Safety Officer (RSO). Audits may be conducted by the RSO, departmental health physicists, trained radiation safety technicians, health physics internship personnel, or other temporary or part-time staff employees specifically trained by an experienced departmental health physicist. Departmental radiation safety auditors may employ the use of a departmental radiological safety audit checklist when performing audits."

Thank you for your time, effort, patience and consideration in this renewal request. Please do not hesitate to contact me at Radiation Safety Service [(313)764-4420] should you have any questions , comments, or concerns regarding this additional information/clarification of this renewal request.

Sincerely,

Mark L. Driscoll

Mark L. Driscoll
Director/Radiation Safety Officer
Radiation Safety Service

MLD/cmb
NRC04B

cc: Henry C. Griffin, Ph.D., Chairman
Radiation Policy Committee

William B. Krumm, Associate Vice-President
Business Operations

Kenneth C. Schatzle, Director
Occupational Safety & Environmental Health