

November 28, 1987

Dr. A. Bert Davis  
Regional Administrator  
U.S. Nuclear Regulatory Commission  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

Dear Dr. Davis:

As the recently appointed President of Case Western Reserve University, I was distressed to learn Wednesday afternoon that radiation safety procedures here had become a matter of concern to your agency. We acted immediately to suspend voluntarily all research use of radioactive materials under our NRC license, effective midnight on Monday, November 30, 1987. We will not authorize our researchers to resume use of these materials until we are confident that appropriate procedures are in effect. This involves reviewing and, where necessary, modifying our existing procedures, tasks in which our staff is engaged as I write this letter to you.

Note that the Monday effective date reflects the fact that when your office's call arrived on Wednesday, many of our principal investigators and other key staff had already left campus -- and in many cases also left the Cleveland area -- in anticipation of the four-day Thanksgiving weekend. Had this all happened on a regular Wednesday, we would have been able to complete arrangements within a day or so. As it is, we have pressed many of our staff into service over the holiday to reach department chairmen, investigators and others involved with the more than 300 research projects affected by our suspension.

You and your colleagues are scheduled to meet with a team of our people at your offices on Monday, November 30, to review the concerns raised about the University's radiation safety procedures. I appreciate your willingness to make time available for such a discussion on short notice -- as you can imagine, the effect of disrupting research projects is potentially very serious. Our team will be headed by Mr. R. James Henderson, who is our Vice President for Finance and Administration and thus my principal deputy for non-academic operations. Under his leadership, the team is authorized to speak for me in their discussions with you.

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Office of the President

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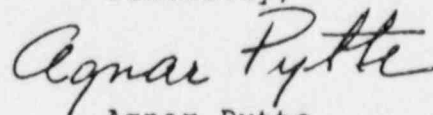
Dr. A. Bert Davis  
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While I am sure that Mr. Henderson will mention this when he visits your office, there is one point that I want you to have directly from me. My career as a teacher and researcher has been in the field of theoretical physics, and specifically in nuclear fusion. Personally, professionally, and now administratively as President of this University, I am committed to complying with all pertinent radiation safety procedures. I understand the importance of these procedures and their relationship to research, and I am determined that we will take whatever steps are appropriate to address the concerns the NRC has raised. If the Monday meeting ends without removing all barriers to a prompt resolution of this situation, I want to know about them so that I can do what is needed at this end to eliminate them.

Thank you again for making the time available to meet with our representatives. I look forward to hearing the outcome of that visit.

Sincerely,

A handwritten signature in cursive script that reads "Agnar Pytte". The signature is written in dark ink and is positioned above the printed name and title.

Agnar Pytte  
President

cc: Mr. R. James Henderson

# SUMMARY OF N.R.C. CONCERNS AND RESPONSES BY CASE WESTERN RESERVE UNIVERSITY

November 28, 1987

This document has been prepared for the purpose of facilitating discussions between N.R.C. officials and representatives of CWRU on Monday, November 30 regarding the resolution of specific concerns expressed by N.R.C. resulting in the suspension by CWRU of activities conducted pursuant to N.R.C. license 34-00738-04.

The items listed herein have been compiled from notes taken during an exit interview conducted by the N.R.C. inspection team on November 24 and from telephone discussions with N.R.C. Region III personnel on November 25.

Any variance between these items and the written report of the N.R.C. investigations, which CWRU expects to receive, will, of course, be reconciled.

Although CWRU has not received the written report and has not had the opportunity to confirm the facts underlying these concerns, CWRU has assumed that the concerns and facts related to us are accurate for the purpose of responding immediately to the N.R.C.

On this basis, CWRU has reviewed its pertinent safety procedures and has made, or is in the process of making, as indicated herein, various changes in its rules and procedures in order to assure that an adequate safety program is in existence for N.R.C. licensed activity at CWRU.

## Items

1. Based upon the University's September quarterly inventory, we are in possession of 70 millicuries of Sr-90 in excess of our current possession limit.

ACTION: At present, our license authorized the possession of 1,030 millicuries of Sr-90. Our September inventory, a summary copy of which was furnished to N.R.C. representatives during their audit, reflects the fact

that we possessed 1,000.5591 millicuries at the time of that inventory. No action is believed to be necessary at this time.

2. The present Chairman of the University Radiation Safety Committee is at variance with that designated in our current license.

ACTION: Dr. Earle C. Gregg, designated Chairman in our license, is now deceased and has been replaced by Mr. Robert B. Adams. Failure to obtain approval of this change was an oversight on our part. We have submitted a request for an amendment to our current license to correct this discrepancy.

(See Exhibit A.)

3. Primary Investigators requesting approval as users under our license are currently reviewed by the Radiation Safety Officer and approved by the Chairman of the University Radiation Safety Committee, not by the full Committee.

ACTION: Our Radiation Safety Handbook states that the Application for User Certification must be processed by the Office of Security & Environmental Affairs (RSO) and by the University Radiation Safety Committee. Additionally, the form, itself, states "Approved by: -- Chairman Committee". In our letter to you dated April 18, 1980, however, we stated that Primary Investigators must be certified by the Committee. Note: We have

always assumed that approval by the Chairman (as denoted on the form) was an acceptable procedure and that he was acting for the Committee. This procedure has been discussed and found to be acceptable during past N.R.C. audits. In view of the apparent conflict at this time, however, we have implemented a procedural requirement that all future certifications must be signed off by the Chairman as well as individually by a majority of the Committee members.

(See Exhibit A.)

4. New technicians handling materials are not trained in accordance with license requirements.

ACTION: The Radiation Safety officer will provide training periodically during the year for all new personnel as well as annual training sessions for the purpose of retraining all technicians and other support personnel engaged in licensed activities. In addition, the principal investigator will be asked to certify on his "Application for Non-Human Use of Radioisotopes" that the people listed to be working with the materials have been trained or retrained in radiation safety within the previous twelve months. The principal investigators will also certify that any new technician who is to be subsequently assigned to work with licensed materials either must show evidence of previous training, or must receive training prior



to the new technician being allowed to work with licensed materials. The Principal Investigator must also submit a revised application form listing the new technician, and this application must be approved before the new technician begins working with such material. (See Exhibit A.)

5. Animals which had been administered radioactive materials in our Animal Resource Center did not have required radioactive-materials cage labeling.

ACTION: Mr. Robert Voigt, Director of our Animal Resources Center, accompanied the N.R.C. inspectors on a tour of his facilities, along with a member of the RSO's staff. No animals without proper cage labeling were discovered or noted by either Mr. Voigt or the RSO representative. Mr. Voigt has subsequently performed a physical inspection along with a review of his records and has no evidence that any animals in improperly marked cages exist. Action on this item must be deferred pending clarification or discovery of the source of the noncompliance item.

6. The Radiation Safety Committee did not meet quarterly as required.

ACTION: Past practice followed was to meet at least four times per year, but not in all cases quarterly. A procedure has been established to pre-schedule the quarterly meetings. Any adjustment to those scheduled dates will only be allowed if the quarterly requirement is maintained. (See Exhibit B.)

7. No survey procedures have been established by P. I.'s for individual laboratories.

ACTION: Principal investigators will be asked to prepare a written survey procedure and to certify on the "Application for Non-Human Use of Radioisotopes" form that such a procedure has been prepared and has been reviewed with laboratory personnel. (See Exhibit A.)

8. Primary Investigator survey instruments in some cases are not being calibrated every 12 months.

ACTION: The form "Application for Non-Human Use of Radioisotopes" is being amended to add a certification that instruments have been calibrated within the last 12 months. This item of compliance will be checked during semi-annual laboratory surveys, as well as during the newly established "walk thru" inspections of each laboratory to be performed at least once in every 60 day period. (See Exhibit A.)

9. Presence of food, beverages, smoking and cosmetics in laboratories with licensed activities.

ACTION: These safety rules will be emphasized during radiation safety training and audited during laboratory inspection and surveys.

10. Emergency procedures not posted in all laboratories where licensed activities are performed.

ACTION: On November 27, 1987, all laboratories were visited and any posting discrepancy was corrected. In the future the same inspections described in No. 8 above will assure compliance.

11. Some personnel were not wearing a laboratory coat while engaging in licensed activities in laboratories.

ACTION: This rule will be emphasized during radiation safety training and audited during laboratory inspection and surveys.

12. Some personnel did not have an appropriate (ring) badge when engaging in licensed activity.

ACTION: This requirement will be emphasized during radiation safety training and audited during laboratory inspections and surveys.

13. Laboratory coats were worn to cafeteria.

ACTION: The six inspections a year will include cafeterias.

14. Primary Investigator for Room 471 in Rainbow Babies and Childrens did not control who entered laboratory where licensed activities were performed.

ACTION: Licensed activity in this laboratory was suspended by the University prior to the recent N.R.C. inspection. The personnel in this laboratory will receive training in the applicable safety requirements before this laboratory is permitted to resume licensed activity. In addition this safety rule will be emphasized during radiation safety training and audited during laboratory inspections and surveys.



15. The Radiation Safety Committee did not review the radiation safety program once per year.

ACTION: The program was reviewed over four quarterly meetings. The July meeting has now been established as the meeting in which to review the entire program.

(See Exhibit B.)

16. A technician was allowed to purchase licensed material in the name of the Primary Investigator.

ACTION: The Purchasing Department will not process any radioisotope purchase requisition without the signature of the authorized Principal Investigator.

(See Exhibit C.)

17. Semi-annual laboratory surveys were not performed on a timely basis.

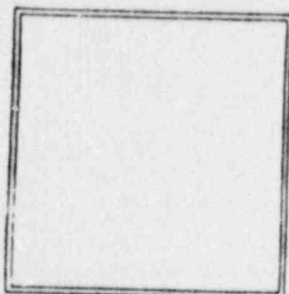
ACTION: The changes in organization, additional personnel and management systems for scheduling and accountability will assure compliance.

18. Radiation Safety Handbook not available in all laboratories.

ACTION: On November 27, 1987 a Radiation Safety Handbook was placed in every laboratory. Its continued presence will be checked during laboratory inspections and surveys.

MEMORANDUM

November 27, 1987



TO: CWRU DEPARTMENT CHAIRMEN

FROM: ARTHUR P. LEARY, ADMINISTRATIVE VICE PRESIDENT *APL*

SUBJECT: SUSPENSION OF RESEARCH ACTIVITIES INVOLVING RADIOACTIVE MATERIAL

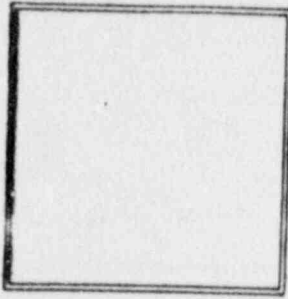
This memorandum confirms the telephone conversation I had yesterday with virtually all of you.

1. The Nuclear Regulatory Commission is alleging that CWRU is deficient in some of its radiation safety procedures. While we are in the process of investigating these allegations we have agreed to suspend further research activities employing radioactive material pending review (and modifications, if indicated) of our procedures and our appeal to the N.R.C.
2. Consequently, it is necessary for each Chairman to notify those investigators in his or her department who perform such research that they must suspend such activities as quickly as possible -- but no later than 11:59 P.M., November 30, 1987. Those investigators listed by the Office of Security & Environmental Affairs of the University from your department are shown in the list enclosed with this memorandum. It is your responsibility to inform the office of Thomas Bozich, Director, Security & Environmental Affairs, by 5:00 P.M., Monday, November 30, 1987 (extension 2906) that you have personally contacted each relevant investigator and instructed him or her to suspend activities no later than midnight, November 30, 1987. In the event that an investigator is unavailable before that time, you are to inform that investigator's colleagues or technicians so they will know not to proceed with the research.
3. Effective December 1, 1987, no activities authorized under CWRU's N.R.C. license may take place in your laboratories. All licensed radioactive materials are to be stored in a safe manner.
4. This suspension will remain in effect until the N.R.C. determines that an adequate radiation safety program is in place.
5. A team from the University, headed by Vice President James Henderson, will be meeting with the N.R.C. in Chicago on Monday, November 30, 1987.
6. We regret the unfortunate delays, inevitable inconveniences, and research loss this will cause you and hope that we will be able to resume normal operations in a short time. Please direct any questions to my office or to Thomas Moss, Dean of Research and Graduate Studies. Thank you for your cooperation.

APL/mm

Encl:

Office of the Vice President for Finance and Administration



November 28, 1987

Mr. Robert G. Gallagher  
Applied Health Physics, Inc.  
2986 Industrial Blvd.  
Bethal Park, Pennsylvania 15102

Dear Bob:

This will confirm our telephone conversation of November 28, 1987 in which you agreed to provide a training session on December 2 and 3, 1987 here at Case Western Reserve University.

As we discussed, we will be training all of our laboratory support personnel who do not meet current minimum standards, along with other support personnel and Primary Investigators who may wish to attend.

I will be in contact with you by telephone to coordinate the arrangements.

Sincerely,

Thomas A. Bozich, Director  
Security & Environmental Affairs

November 28, 1987

TO: Thomas A. Bozich, Director of Security & Environmental Affairs

FROM: Arthur P. Leary, Administrative Vice President

Subject: RADIATION SAFETY PROGRAM

As a result of our discussions with the N. R. C. and in keeping with our commitment to upgrade our radiation safety program, the following changes are effective immediately:

1. Until further notice you are relieved of your responsibility for police and security functions so that your full attention can be directed to our safety programs. An effective program in radiation safety is our top priority.
2. You are authorized to recruit and hire two additional staff members to work exclusively in radiation safety. One of these individuals should be a professional, preferably with training and experience in health physics. The immediate goal is to have three F.T.E. staff working in this area in addition to yourself. I want you to expedite this search and I stand ready to assist in the process.
3. Our radiation safety program must be strengthened with good systems, procedures and controls. It is essential that the system include schedules, assignments and management reports. I stand ready to provide hardware/software support to accomplish this. You might confer with your colleagues at other institutions to see if someone has in place an excellent system we might copy. I want a plan in place by January 15.

APL:ve  
cc: R. J. Henderson

RADIATION SAFETY SURVEY  
VERIFICATION

LABORATORY \_\_\_\_\_

- \_\_\_\_\_ 1. A semi-annual survey has been performed at this laboratory since August 1, 1987, and the survey indicates that there are no deficiencies, or any deficiencies identified by the survey have been corrected and such corrections have been verified by the Radiation Safety Office.
- \_\_\_\_\_ 2. The Primary Investigator has certified, subsequent to November 20, 1987, that all personnel working in this laboratory meet the applicable training requirements.
- \_\_\_\_\_ 3. Radiation survey instrumentation in the laboratory has been calibrated within the past 12 months.
- \_\_\_\_\_ 4. The NRC has not advised the licensee that any deficiencies exist in this laboratory; or any deficiencies identified by the NRC with respect to this laboratory have been corrected, and such corrections have been verified by the Radiation Safety Office.

The above listed laboratory is hereby authorized to resume activity authorized by NRC license 34-00738-04 as of the below listed date.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Radiation Safety Officer