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August 17, 1982

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West Virginia University
ATTN: Mr. E. Gordon Gee, President
Morgantown, WV 26506

Gentlemen:

Subject: Report Nos. 47-01163-20/82-01 and 47-01163-22/82-01

Thank you for your letter of July 29, 1982, informing us of steps you have taken to correct the violation concerning activities under NRC License Nos. 47-01163-20 and 47-01163-22 brought to your attention in our letter of June 30, 1982.

Concerning your performance of direct radionuclide cystography, under License No. 47-01163-20, items 6.H, 7.H, 8.H, and 9.H restrict such use to "medical research" in humans, under approval of your FDA Radioactive Drug Research Committee. 10 CFR 35.100(c)(5) permits "diagnostic use" in humans under an FDA accepted IND.

It would appear that your institution can proceed with "medical research" in this area without further application to either the FDA or the NRC.

We appreciate your cooperation with us.

Sincerely,

(original signed by AFGibson)
A. F. Gibson, Chief
Technical Inspection Branch
Division of Engineering and
Technical Programs

bcc: Document Management Branch
State of West Virginia

for RII [Signature]
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