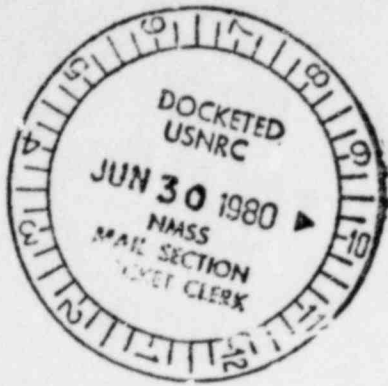


PDR

71-0121



# NEUTRON PRODUCTS inc

Dickerson, Maryland 20753

U. S. A.

301/349-5001 TWX: 710-828-0542

June 24, 1980

Mr. Charles E. MacDonald, Chief  
 Transportation Certification Branch  
 Division of Fuel Cycle and Material  
 Safety, NMSS  
 U. S. Nuclear Regulatory Commission  
 Washington, D. C. 20555

Dear Mr. MacDonald:

In accordance with your April 23, 1980 letter, enclosed please find seven copies of Revision 3 of the Quality Assurance Program for Neutron Products, Inc. (NPI).

Attached to this letter is a summary that addresses item by item the request for additional information which you transmitted with your April 23 letter. Items 2, 5, and 14 of the request for additional information were addressed by directly modifying the QA program. These changes are underlined.

If there are any questions regarding this submittal, please feel free to contact me at 301/428-9819.

Sincerely,

NEUTRON PRODUCTS, INC.

*Carmine Smedira*  
 Carmine Smedira  
 Quality Assurance Manager

Enclosures

CS/bms

RECEIVED  
 JUN 30 11  
 U.S. NUCLEAR REGULATORY COMMISSION  
 MAIL SECTION

NPI Response to Additional Information  
Requested by NRC With Respect to NPI QA

1. The NPI QA program states that "The Quality Assurance Manager must have a sufficiently broad education and experience to be able to interpret the requirements of all regulatory agencies to all aspects of the company's operations." The implementing criteria used by NPI management in the selection of QA managers are:
  - (a) reasonably extensive nuclear project experience;
  - (b) some experience in dealing with regulatory or safety requirements; and,
  - (c) demonstrated writing skills.

To date, NPI QA managers have been degreed engineers or scientists. While we do not intend to make a degree a requirement, most people who meet the above criteria are degreed.

The present QA Manager is a degreed nuclear engineer with 12 years of nuclear project experience. The majority of his time in the last year has been devoted to trying to assure that company activities are in compliance with State of Maryland, Nuclear Regulatory Commission, Department of Transportation, Food and Drug Administration, and other regulatory and safety requirements.

2. See QA plan modification page 40.
3. Safety related systems, structures and components controlled by the QA program:
  - (a) All NPI shipping containers for radioactive materials
  - (b) Customer teletherapy units serviced by NPI
  - (c) Dickerson I and Dickerson II irradiators
  - (d) Customer laminar flow equipment serviced by NPI
4. Under the interpretation that a prototype unit is a full scale, full feature component of a system or structure to be put into service, NPI does not build prototype units. Instead of prototype units, the actual system or structure has been built and proof tested before being placed in service.
5. See QA plan modification page 1a.
6. NPI does not manufacture equipment. Consequently NPI identifies and controls materials, parts and components used in manufacturing through control of procurements (see Procurement Document Control, Control of Purchase and Material, Equipment, Services, Etc. in each subplan of the overall QA program).
7. We believe this is covered in Section 17 of each subplan of the overall QA program.

8. In view of the relative simplicity of materials and parts important to the function of safety related systems and components associated with NPI activities, NPI does not maintain complete documentation of the actual materials and parts used in safety systems. Instead, the adequacy of the materials and parts used is usually readily ascertained while in service or under a routine inspection. Documentation of the required functions of safety systems is maintained. For example, safety systems on NPI irradiators make extensive use of limit switches and relays whose performance is routinely checked. We do not verify the materials used in manufacturing the relays and switches. We have documented the required performance of these systems.
9. NPI management recognizes the role that good judgement of responsible employees plays in making a QA program successful. Consequently, we do not have a statement in our QA program to the effect that the method of identifying an item should not affect the fit, function, or quality of the item. To date, this has not been a problem.
10. The comment we made with respect to item 6 above would appear to be appropriate here also.
- 11, 12, 13. Section 11 of each subplan of the overall QA plan covers special processes appropriate to that aspect of NPI operations. These subsections require procedural controls and personnel qualification as appropriate. Section VI of the plan states that NPI shall maintain Personnel Qualification Approval and Certification records.
14. See QA plan modification page 41.