

"QUALITY ASSURANCE PROCEDURE FOR ONE-TIME RESEARCH AND DEVELOPMENT WORK"

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SUPERSEDED

Ron Makela
PREPARED BY

4/11/85
DATE

Paul R. Githals
INC DIVISION

5/3/85
DATE

C.W. Myers
ESS DIVISION

4/19/85
DATE

DC Nelson
WX DIVISION

5/11/85
DATE

Fred Guyker
E-DIVISION

5/8/85
DATE

J. Dally
TECHNICAL PROJECT OFFICER

5-14-85
DATE

Ron Makela
QUALITY ASSURANCE APPROVAL

5/22/85
DATE

"Quality Assurance Procedure for One-Time Research and
Development Work"

INTRODUCTION

It is recognized that because of the unique nature of research and development special considerations must be made in applying NVO 196-17 criteria to a research and development program.

Research and development must be conducted in advance of formal procedures and tests and continual modifications must be made when method development is being conducted. This procedure addresses a generic quality assurance program for research and development work.

1.0 PURPOSE AND SCOPE

This procedure shall be used when research and development work must be accomplished in advance of a formally approved work plan and/or procedure, "one-time" research and development. Work accomplished in accordance with this procedure cannot be used to support NNWSI licensing (Level 1) requirements without further upgrading. Upgrading must meet the criteria given in NVO-196-17.

2.0 APPLICATION

While all 18 criteria of ANSI/ASME NQA-1 may not be applicable for "one-time" research and development, fundamental requirements must be met.

2.1 Laboratory Notebooks

For research and development work accomplished in advance of established procedures and/or work plans, the laboratory notebook shall be the primary source of documentation.

Brief statements of the planned method (approach) shall be noted in the notebook prior to the actual work being conducted. As the test evolves and changes in testing are required, the proposed changes shall be described in the notebook. The sequence of events documented in the notebook must provide enough detail so that a knowledgeable person performing a peer review can review the incremental steps taken, follow the course of events and understand the changes made during testing.

2.2 Procurement of Items and Equipment

Laboratory equipment procured for research and development work need not be procured through an approved vendor if the equipment will be used in Level 2 or 3 activities. Equipment that is procured for research and development work must be upgraded, if possible, to conform to the requirements of NVO-196-17, or additional equipment must be procured from an approved vendor if it is to be used in a Level 1 activity.

2.3 Calibration of Equipment

Equipment that requires calibration shall be calibrated in accordance with the manufacturer's manual or as appropriate. The interval of calibration shall be established by the principal investigator, subject to review and approval by technical and quality assurance management. When possible, the calibration shall be traceable to NBS standards.

Equipment calibration records shall be maintained in accordance with TWS-MSTQA-QP-09.

2.4 Handling, Shipping, and Storage

The handling, shipping, and storage of research and development samples shall be accomplished with appropriate care. If, however, the sample is to be used as part of a Level 1 test at a later date, then the appropriate Level 1 technical and quality assurance procedures must be complied with.

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