



Nuclear  
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May 14, 1986

Mr. Dennis P. Allison  
Office of Inspection & Enforcement  
US NRC - Mail Stop EWW507  
Washington, DC 20555

Subject: Definition of Commercial Grade Item; 10 CFR Part 21 and  
ANSI/ASME NQA-1

Dear Mr. Allison:

An item has arisen within ASME nuclear codes and standards activities concerning the definition of commercial grade item in 10 CFR 21 and ANSI/ASME NQA-1 "Quality Assurance Requirements for Nuclear Facilities." I am writing to you since I understand your section and staff are responsible for proposed rule changes to 10 CFR 21. I would first like to provide some background on ASME's consideration and then request NRC staff consideration of the item.

The ANSI/ASME NQA-1 Standard is the product of many years of effort to coordinate and consolidate voluntary consensus quality assurance requirements for the nuclear industry. ANSI/ASME NQA-1 consolidated the N45.2 Standards series, and through cooperative effort with AICHE, the N46 Standards series. The inclusion of the N46 Standards, which have since been withdrawn as American National Standards, resulted in the expansion of scope from nuclear power plants to nuclear facilities.

During public review of the 1a-1983 Addenda to NQA-1, it was commented that the definition of commercial grade item included in the Addenda was overly restrictive and would result in difficulties when applied to nuclear facilities other than power plants, such as fuel reprocessing plants. The Committee on Nuclear Quality Assurance (NQA) which is responsible for the development and maintenance of NQA-1, took action to revise the definition in Supplement S-1 as shown on the attached page.

The proposed revision proceeded to the ASME Board on Nuclear Codes and Standards (BNCS) and failed on first consideration. The Board deemed it essential that the definitions be identical. However, it was felt there should be no difficulty in NQA inclusion of clarifying statements within the text of its Standards to the effect that "facilities" can be either nuclear power plants or fuel reprocessing plants. Additionally, any "special requirement" which one plant may optionally decide to impose,

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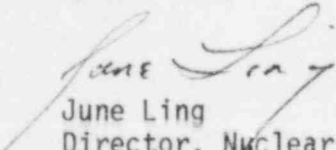
does not necessarily impact on the "commercial grade" status of the item for all plants. It was felt this was not in conflict with the definition, nor application of the definition, as contained in 10 CFR 21.

The Board recommended the above course of action to the NQA Committee based on the need to keep definitions identical. The purpose of this letter is to request appropriate NRC staff consideration of an NQA Committee suggested revision to the definition contained in 10 CFR 21. The proposal is to revise 10 CFR 21.3 (a)(4)(a-1) to read "... (1) not subject to design or specification requirements that are unique to the nuclear facility or activity licensed pursuant to Parts...".

Regarding 10 CFR 21, it is my understanding a proposed revision is well along the process within NRC, but does not pertain to this particular item. Perhaps, as a means of obtaining early clarification, the Committee on Nuclear Quality Assurance should submit a public comment delineating application of the definition in ANSI/ASME NQA-1 when the proposed rule change to Part 21 is released. The response would reflect what I understand to be the case, i.e. the NQA Committee's use of the definition in ANSI/ASME NQA-1 is not in conflict with the intent of Part 21.

This letter is intended as informal communication between NRC staff and ASME. We will not pursue petition for rulemaking, however we would appreciate NRC staff consideration of the proposed revision.

Yours truly,



June Ling  
Director, Nuclear  
Codes and Standards  
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JL/cj  
Attachment

cc: L. J. Chockie - BNCS Chrmn.  
E. J. Hemzy - BNCS Vice Chrmn.  
J. A. Perry - NQA Committee Chrmn.  
S. D. Weinman - ASME Staff Secretary - NQA  
G. A. Arlotto  
G. G. Zech  
M. Malloy  
R. Singh

SUPPLEMENT S-1  
TERMS AND DEFINITIONS

## 1 GENERAL

This Supplement contains definitions of certain quality-related terms used in this Standard or in ANSI/ASME NQA-2.

## 2 TERMS AND DEFINITIONS

*Acceptance Criteria.* Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

*Audit.* A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

*Certificate of Conformance.* A document signed by an authorized individual certifying the degree to which items or services meet specified requirements.

*Certification.* The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

*Characteristic.* Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

*Commercial Grade Item.* An item satisfying (a), (b), and (c) below:

(a) not subject to design or specification requirements that are unique to nuclear facilities;

(b) used in applications other than nuclear facilities;

(c) is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, catalog).

*Condition Adverse to Quality.* An all inclusive term used in reference to any of the following: failures, mal-

the nuclear facility;

The definition proposed in NQA-1 is technically identical to 10CFR Part 21.3 except for item (a) where we refer to "unique to the nuclear facility." Part 21 states "unique to facilities." Part 21 only applies to facilities licensed by the NRC and as such relates to "safety related items." NQA-1, on the other hand, is not bound by applications limited to regulations, nor is it restricted to "safety related items." The reason for the change in wording in NQA-1 was brought about in response to a public inquiry with supporting justification that a given nuclear facility (i.e., fuels reprocessing) could have a commercial grade item that was not unique to that specific facility, although when used in a power plant application, could have unique requirements. This change was made after considerable deliberation and discussed with the inquirer. We have concluded the comment by the inquirer was valid based on the scope and application of this standard and strongly recommend that the BNCS approve this item as submitted.