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June 13, 1991
LD-91-029

Docket No. 52-002

Mr. E. William Brach, Chief
Performance and Quality Evaluation Branch
U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555

Subject: Updates to Topical Report CENPD-210, Revision 6

Reference: Letter LD-91-009, E. H. Kennedy (C-E) to
T. V. Wambach (NRC), dated February 13, 1991

Dear Mr. Brach:

Enclosure I contains marked-up pages of CENPD-210, Revision 6 (Reference). The changes are provided to resolve comments discussed between Mr. J. Pasquenza of Combustion Engineering and Mr. J. Spraul of your staff. Enclosure II contains a complete copy of CENPD-210, Revision 6 which incorporates the above changes (see pages 11, 12, 24 and 42).

We believe that the submission of these updates will permit the NRC to approve CENPD-210, Revision 6.

If you have any questions, please call me or Mr. J. P. Pasquenza at (203) 285-2696.

Very truly yours,

COMBUSTION ENGINEERING, INC.

E. H. Kennedy

Ernie H. Kennedy
Manager
Nuclear Systems Licensing

EHK:lw
Enclosures: As Stated

cc: P. Lang (DOE - Germantown)
J. Spraul (NRC)
T. V. Wambach (NRC)

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Enclosure I to
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This enclosure contains pages (numbered 9, 10, 21 and 38) from the previous version of CENPD-210, Revision 6, which are marked up to show proposed changes.

These procedures provide specific instructions for accomplishment of design activities by defining requirements for design inputs and outputs including:

- o document format and content,
- o document identification,
- o review and approval,
- o design verification,
- o issuance and distribution,
- o revision control,
- o indication of document status,
- o record retention.

The procedures apply to design/engineering activities including such disciplines as reactor physics; stress, thermal, hydraulic and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; fuel design; instrumentation and controls design; and delineation of acceptance criteria for inspections and tests.

The procedures cover the total design process to assure that:

- o appropriate design basis requirements including quality standards are selected, specified, and included in the design;
- o deviations from standards are controlled;
- o materials, parts, equipment, and processes (including commercially obtained items) essential to the safety-related functions of basic components are reviewed for suitability of application and compatibility with overall system design criteria;
- o design interfaces among participating organizations (both internal and external) are identified and controlled;
- o design work is verified or checked for adequacy;

delete — appears on top of pg 10.

- o design work is verified or checked for adequacy;
- o design changes, including field changes, are subject to the same degree of control as applied to the original work.

Compliance to design control procedures is monitored by NQ internal compliance audits.

III.3.2 Design Inputs

Design work begins with the definition of the design requirements or design bases information. These requirements come from several sources. Typical sources include previously approved designs, those from engineering and product development efforts, contracts (eg., equipment performance criteria, design life, regulatory requirements, codes and standards, interface requirements, etc.), Standard Safety Analysis Reports, topical report, and information from industry or government funded research activities.

A Project/Task Manager (or equivalent) supplies the Cognizant Organization(s) (CO) with the design requirements or design bases and applicable quality requirements that are specified in contract documents, bid specifications, regulations and industry standards as applicable to the respective efforts. Within the CO, specific tasks are established and assigned to cognizant engineers. The CO is responsible for selection and documentation of design inputs including the identification, substantiation and documentation of changes from previously approved designs.

The CO assures that design inputs have been verified or annotated to clearly indicate data or assumptions that must be confirmed by later design efforts or tests and that the design inputs are traceable by reference to the source of the data.

these were inadvertently omitted →

Design documents containing input data are approved by the author and verifier(s) of the documents

and alternatives

Table III-3

Clarifications to NQA-1 and/or Regulatory Guide 1.28 (Rev. 03)

Section	~~Clarification~~
Regulatory Guide 1.28 Paragraph C. 1 Clarification	Training procedures are used to ensure that individuals are qualified in a manner commensurate with the requirements of their job description. Operating procedures ensure that activities are accomplished at the correct inspection/organization level. This may be used in lieu of personnel level ratings.
Paragraph C.3.2.1 alternative	The frequency of auditing a supplier is based on: i) if active work is in progress under a purchase order, ii) results of quality trend evaluations, iii) quality classification of item or service, iv) processes being employed, v) item or service complexity or uniqueness, vi) number of planned surveillances, vii) number of current orders.
NQA-1 Supplement 17S-1 Paragraph 2.3 Clarification	Record validation/authentication is by identification in procedures and logging.
Paragraph 4.0 Clarification	Applies only to records transferred to permanent storage (all other records are classified as "working" files). "Working" files are controlled to assure adequate preservation and safe keeping while awaiting transfer to permanent storage, or the client, or expiration of retention requirements.

Replace with insert 1

The procurement of spare or replacements parts and components are governed by client order requirements.

For commercial-grade items which are supplied as safety-related, but where specific QA control cannot be imposed in a practical manner, specific provisions are made during receiving inspection or source surveillance to verify that critical characteristic are met.

Initial supplier approval is via survey or evaluation that is conducted by NQ. The purpose of ~~these are~~ this is to verify that the new supplier is capable of complying with the quality requirements in the procurement documents. The results are documented and any identified deficiencies are resolved prior to starting work. IN ACCORDANCE WITH IE INFORMATION NOTICE 86-21, SUPPLIERS THAT HAVE RECEIVED ASME APPROVAL ARE CONSIDERED "APPROVED SUPPLIERS" ON THE BASIS OF THE ASME APPROVAL

Supplier approval is maintained by annual evaluations and periodic audits. The annual evaluations take into consideration items such as supplier furnished documentation; results of prior surveillances, inspections, and audits, and item or service operating performance. The periodic audits ADDRESS THE APPLICABLE CRITERIA OF 10CFR50 APP B and are normally performed on a triennial basis, AN ALTERNATIVE TO ~~and are consistent with~~ the guidance in paragraph ~~Para~~ C.3.2.1 of Regulatory Guide 1.28 (Rev. 3). ~~The scope and frequency of audits depends on many factors such as the~~ IS given in Table III-3. ~~The audits address the applicable criteria of 10CFR50 Appendix~~ B.

~~Suppliers that have received ASME approval are approved on the basis of the ASME approval.~~

For items shipped to a ABB Combustion Engineering Nuclear Power manufacturing or warehouse facility, receiving and/or source surveillance procedures are used to assure that the item and specified documentation comply with the procurement document requirements. Measures are established to assure that items accepted and released are identified as to their inspection status in order to prevent the use or installation of non-

TABLE III-3 REVISION

Alternative

[redacted] TO REG GUIDE 1.28, PARAGRAPH C.3.2.1:

An audit of approved suppliers' quality assurance program is conducted on a triennial basis unless:

i) there is no active work in progress (note: auditing will resume when work resumes); or

ii) documentation reviews and surveillances and/or inspections and/or independent tests [redacted] show acceptable quality assurance program implementation; or

iii) the procurement is for ASME Code items from suppliers that hold valid ASME Certificates of Authorization or Quality Systems Certificates. In this case acceptable quality assurance program implementation will be verified by one or more of the following depending upon procurement scope and complexity:

a) audit
b) surveillance
c) inspection
d) independent test
[redacted]

documentation review and

Insert 1

Enclosure II to
LD-91-029

This enclosure presents CENPD-210, Revision 6, including the changes of Enclosure I.