

AUG 12 1992

Docket No. 99901227

Mr. R. S. Orr  
Nuclear Administrator  
Mail Stop 7A-47  
Boeing Computer Services  
P. O. Box 24346  
Seattle, Washington 98124-0346

Dear Mr. Orr:

SUBJECT: RESPONSE TO 10 CFR PART 21 INQUIRY

By letter dated June 12, 1992, you requested the U. S. Nuclear Regulatory Commission's (NRC) position regarding your unsuccessful attempt to contact certain former Boeing customers to inform them of error notices received from your former suppliers of nuclear related codes.

We have described our position in Enclosure 1 to this letter. The current revision to 10 CFR Part 21 dated July 31, 1991 is also provided for your information as Enclosure 2. The latest address and phone number information on file at the NRC for the requested companies is provided as Enclosure 3.

Should you have any further questions, please contact Mr. Ronald Frahm, Jr. of my staff at (301) 504-3216.

Sincerely,

Leif J. Norrholm, Chief  
Vendor Inspection Branch  
Division of Reactor Inspection  
and Safeguards  
Office of Nuclear Reactor Regulation

Enclosures:

1. Response to Questions
2. July 1991 Revision to 10 CFR Part 21
3. Customer Address Information

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RESPONSE TO BOEING COMPUTER SERVICES LETTER

QUESTION (paraphrased):

Does the NRC require: (1) a copy of every supplier error notice on the enclosed list which was not received by a former customer and (2) a copy of every future error notice received by Boeing which is not sent to one or more former customers?

NRC RESPONSE:

Part 21 to Title 10 of the Code of Federal Regulations (10 CFR Part 21) requires that suppliers of basic components, or services associated with basic components, evaluate deviations or notify the customers if the supplier does not have the capability to perform the evaluation. The intent of 10 CFR Part 21 is to assure that users of basic components are made aware of any potential defects which could create a substantial safety hazard.

Your letter states that Boeing has attempted to inform all of their purchasers when error notices were reported so that the customers could evaluate the safety significance of the deviation. In the cases where Boeing was unable to contact former customers, Boeing should notify the NRC promptly so that the NRC can determine if the deviation is of significance to warrant generic communications to the nuclear industry. The notifications should be made initially via facsimile or telephone communication to the NRC Operations Center followed by written transmittal to the NRC Document Control Desk as detailed in 10 CFR Part 21.

UNITED STATES NUCLEAR REGULATORY COMMISSION  
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS — ENERGY

ENCLOSURE 2

21.1

21.3(a)

**PART  
21**

**REPORTING OF DEFECTS AND NONCOMPLIANCE**

**GENERAL PROVISIONS**

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Authority: Sec. 161, 68 Stat. 948, as amended, sec. 234, 63 Stat. 424, as amended (42 U.S.C. 2201, 2262); sec. 201, as amended, 206, 88 Stat. 1242, as amended, 1246 (42 U.S.C. 5841, 5846).

Sec. 21.2 also issued under sec. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

For the purposes of sec. 223, 66 Stat. 958, as amended (42 U.S.C. 2273): §§ 21.4, 21.21(a) and 21.31 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 21.21, 21.41 and 21.51 are issued under sec. 161c, 68 Stat. 950, as amended (42 U.S.C. 2201(c)).

**GENERAL PROVISIONS**

**§ 21.1 Purpose.**

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial

safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

**§ 21.2 Scope.**

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 70, or part 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high level radioactive waste, or to construct, manufacture, possess, own, operate or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and to each director and responsible officer of such a licensee. The regulations in this part apply also to each individual, corporation, partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation pursuant to part 50 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to part 72 of this chapter, a MRS for the storage of spent fuel or high level radioactive waste pursuant to part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 60, 61, 70, 71, or part 72 of this chapter.

(b) For persons licensed to construct a facility under a construction permit issued under § 50.23 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects

and failures to comply under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 50.73 or § 73.71 of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

(d) Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (see § 21.3(a-1)) not subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the five regions (answered during regular working hours), are listed in appendix D to part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day—including holidays) is (301) 951-0550.

**§ 21.3 Definitions.**

As used in this part:

(a)(1) "Basic component," when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 100.11 of this chapter.

(2) "Basic component," when applied to other facilities and when applied to

other activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter, means a component, structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect (see § 21.3(d)) or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (see § 21.3(k)).

(3) In all cases, *basic component* includes safety related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

(4) A commercial grade item is not a part of a basic component until after dedication (see § 21.3(c-1)).

(a-1) "Commercial grade item" means an item that is (1) not subject to design or specification requirements that are unique to facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (2) used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example a catalog).

(b) "Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

(c) *Constructing or construction* means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

(c-1) "Dedication" of a commercial grade item occurs after receipt when that item is designated for use as a basic component.

(d) "Defect" means:

(1) A deviation (see § 21.3(e)) in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation (see § 21.3(g)), the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (d)(1) of this section; or

(3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 of this chapter provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to Part 50 of this chapter.

(e) "Deviation" means a departure from the technical requirements included in a procurement document (see § 21.3(i)).

(f) "Director" means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, "director" means the individual.

(g) *Discovery* means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21. (a).

(h) *Evaluation* means the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

(i) *Notification* means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

(j) *Operating or operation* means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety related.

(k) "Procurement document" means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

(l) "Responsible officer" means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

(m) "Substantial safety hazard" means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.

(n) "Supplying" or "supplies" means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

#### § 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

#### § 21.5 Communications.

Except where otherwise specified in this part, all written communications and reports concerning the regulations in this part must be addressed to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555. In the case of a licensee, a copy must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

#### § 21.6 Posting requirements.

(a) Each individual, partnership, corporation or other entity subject to the regulations in this part, shall post current copies of the following documents in a conspicuous position on any premises, within the United States where the activities subject to this part are conducted (1) the regulations in this part, (2) Section 206 of the Energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in this part.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) The effective date of this section has been deferred until January 6, 1978.



**§ 21.7 Exemptions.**

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial grade items.

**§ 21.8 Information collection requirements. OMB approval.**

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0035.

(b) The approved information collection requirements contained in this part appear in §§ 21.21 and 21.51.

**NOTIFICATION****§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.**

(a) Each individual, corporation, partnership, or other entity subject to the regulations in this part must adopt appropriate procedures to—

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(c)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in § 21.21(a)(1) or § 21.21(a)(2) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity—

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect.

(b) If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to § 21.21(a).

(c)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(c)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting—

(i) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.

(2) The notification to NRC of a failure to comply or of a defect under paragraph (c)(1) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.

(3) Notification required by paragraph (c)(1) of this section must be made as follows—

(i) Initial notification by facsimile which is the preferred method of notification, to the NRC Operations Center at 301-492-8187 or by telephone at 301-951-0550 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile

has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.21(a)(2).

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply.

(4) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(5) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(d) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

## PART 21 • REPORTING OF DEFECTS AND NONCOMPLIANCE

## PROCUREMENT DOCUMENTS

## § 21.31 Procurement documents.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall assure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978 specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

## INSPECTIONS, RECORDS

## § 21.41 Inspections.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall permit duly authorized representatives of the Commission, to inspect its records, premises, activities, and basic components as necessary to effectuate the purposes of this part.

## ENFORCEMENT

## § 21.61 Failure to notify.

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

[Note removed 49 FR 19623]

## § 21.51 Maintenance and inspection of records.

(a) Each individual, corporation, partnership, or other entity subject to the regulations in this part must prepare and maintain records necessary to accomplish the purposes of this part, specifically—

(1) Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;

(2) Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification.

(3) Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part must afford the Commission, at all reasonable times, the opportunity to inspect records pertaining to basic components that relate to the discovery, evaluation, and reporting of deviations, failures to comply and defects, including any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

RESPONSE TO BOEING COMPUTER SERVICES LETTER  
BOEING CUSTOMER ADDRESS INFORMATION

The following 3 addresses differed from those you had listed:

ABB Impell Corporation  
5000 Executive Parkway  
San Ramon, CA 94583  
(415) 275-4770

Nuclear Power Services  
One Harmon Plaza  
Secaucus, NJ 07094  
(201) 865-6550

URS/John A. Blume & Associates  
130 Jessie Street  
San Francisco, CA 94105  
(415) 397-2525

The NRC has the same address as Boeing for Reactor Controls, Inc.

The NRC has no information available for Echo Energy Consultants, Inc. in Oakland, California or Nuclear Applications and Systems Analysis Company in Japan.