

UNITED STATES
NUCLEAR REGULATORY COMMISSION

CONSENT CALENDAR ITEM

September 8, 1978

SECY-78-496

For: The Commissioners

From: Robert B. Minogue, Director, Office of Standards Development

Thru: Executive Director for Operations *W.P.*

Subject: 10 CFR PART 21 APPLICABILITY TO NONLICENSEE SUPPLIERS OF
COMMERCIAL GRADE ITEMS

Purpose:

1. Inform the Commission of current impact of 10 CFR Part 21¹ as applied to nonlicensee suppliers of "commercial grade items"² and
2. Obtain Commission approval of a notice of effective rule-making that would impose limits on the applicability of 10 CFR Part 21 to nonlicensee suppliers of such "commercial grade items."

Category: This paper covers a major policy question requiring Commission approval.

Issue: Whether Section 206 of the Energy Reorganization Act of 1974, as amended, is properly and appropriately applied to nonlicensee suppliers of "commercial grade items."

Decision Criteria:

1. Impact of implementation of 10 CFR Part 21 on matters affecting health and safety.
2. Compliance with the statutory provisions of Section 206 of the Energy Reorganization Act of 1974.

¹10 CFR Part 21, "Reporting of Defects and Noncompliance," was approved by the Commission at Policy Session 77-20, March 3, 1977 (SECY-77-73), was published effective June 6, 1977 at 42 FR 28891 and became fully effective January 7, 1978.

²The term "commercial grade item" is fully defined in the attached rule. An abridged definition is that the item is not uniquely applied to nuclear facilities and it is described in manufacturers' product description literature. For example, a "commercial grade item" does not include an item that is uniquely applied to nuclear facilities, e.g., an ASME Section III Class 2 valve, but would include the bar stock material procured and used to fabricate the valve stem of such a valve.

Contact:
W. E. Campbell, Jr.
443-5913

781020 0105

* Alternatives:

1. Maintain the effective 10 CFR Part 21 as it relates to non- licensee suppliers of "commercial grade items."
2. Amend 10 CFR Part 21 to remove from its scope the nonlicensee suppliers of "commercial grade items" for any facility or activity that is licensed or otherwise regulated by NRC.

Discussion:

Background material is contained in Enclosure 1.

Neither Section 206 of the Energy Reorganization Act of 1974, as amended, nor the legislative history provides a definition of a "basic component" supplied to a facility or activity licensed or regulated by NRC. This definition was left to rulemaking by NRC. Enclosure 2 contains the definition, as used in 10 CFR Part 21, of "basic component" and some other pertinent terms used in 10 CFR Part 21.

Almost every item that is specifically designed for nuclear use is composed of some commercial grade items, e.g., a valve stem machined from ASTM specification material or a sealed bearing. Nuclear licensees, and their agents, i.e., architect-engineer (AE) nuclear steam systems supplier (NSSS), are having difficulty in applying 10 CFR Part 21 to these items that can be described as "standard stock," "off-the-shelf," or "commercial grade." These difficulties include significant price increases and refusal by suppliers to either submit a bid or accept orders.

These commercial grade items are usually produced to a set of specifications drafted either by the manufacturer or the industry in anticipation of an order, with no specific end use or application in mind and without traceability to a specific item in the production lot, batch, or heat.

These items may go directly from the manufacturer to an organization that knows the items will be used in a safety-related application or they may go through a series of organizations before the items are received by an organization that has knowledge of the intended use of the items. Many responsible suppliers are refusing even to quote on such commercial grade items if 10 CFR Part 21 is invoked in the procurement document. Additionally, other organizations are refusing orders because they are unable to procure material and parts from which their commercial items are manufactured when they in turn invoke the same

10 CFR Part 21 requirements on their suppliers. Many organizations have refused orders invoking 10 CFR Part 21. (See Attachment B to Enclosure 1.) There are widespread reports that numerous organizations that are currently suppliers to nuclear facilities have refused or may refuse orders which invoke 10 CFR Part 21. (See Attachment C to Enclosure 1.)

The staff has been monitoring the implementation of 10 CFR Part 21 by those subject to the rule. Of particular concern were the reports from those subject to the rule that (1) 10 CFR Part 21 was ambiguous in regard to basic components, (2) the implementation in regard to basic components was impractical and not effective, and (3) the implementation was causing, or about to cause, increased procurement costs without any identifiable improvement of safety. (See Attachment B to Enclosure 1.)

The staff in drafting the current 10 CFR Part 21 realized that all items, organizations, activities, and products involved in the design, construction, or operation of a nuclear facility or activity were not such that they could create a substantial safety hazard. The staff intended that the purchaser would pass the requirements of 10 CFR Part 21 to levels in the procurement chain only where it was applicable, i.e., where the procured item could cause a substantial safety hazard. It was specifically not the intent of the staff to require, by 10 CFR Part 21, additional control of purchased material and equipment beyond that already required, e.g., the implementation of 10 CFR Part 50, Appendix B. However it appears that cautious application of 10 CFR Part 21, by those subject to it, is having an effect opposite to that the staff intended. A possible reason is that the risk of the allowed civil penalty (\$5000 per day) is causing suppliers to pass the 10 CFR Part 21 down another level rather than make the decision that the item being procured could not create a substantial safety hazard.

The staff has been unable to determine if the requirements of 10 CFR Part 21 have been solely responsible for increased prices.

Portions of the nuclear industry believe that the currently effective 10 CFR Part 21, as it relates to suppliers of commercial grade items, remains ambiguous, ineffective, costly and impractical. Subtier suppliers' refusal to accept procurement documents invoking 10 CFR Part 21 appears to be based on one or more of the following reasons: (1) the relatively small volume of commercial grade items produced that ultimately are used in nuclear applications does not justify the potential risk of civil penalty and the requirement to comply with other features of 10 CFR Part 21 such as preparing implementing procedures, (2) the supplier considers

that parts, which must be obtained from subsuppliers, will be difficult or impossible to obtain because of subsuppliers refusing to accept procurement orders that invoke 10 CFR Part 21, and (3) in the distribution of commercial grade items the manufacturer/distributor can provide traceability of the items only for a very limited period of time, that is, identification of where all items of a specific production run are.

Some segments of the staff and industry believe that new suppliers of commercial grade items will attempt to enter the nuclear market place as some of the present suppliers may depart. These new suppliers will probably be able to ask for and receive a high price - high enough to cover their 10 CFR Part 21 liability as they perceive it - because the item is needed for continued power generation capability. To assure that the item from a new supplier meets the necessary requirements and to upgrade the new supplier, it will be necessary for the purchaser to allocate significant additional resources. Even with the additional resources required, there will likely be less assurance that the item will satisfactorily perform its function when compared to the item produced by the original supplier. Such a condition may be adverse to health and safety.

Alternative 2 has been developed based on the perceived understanding of the intent of Congress and proposes to resolve the issue of applicability of 10 CFR Part 21 to suppliers of "commercial grade items" by excluding such organizations from the scope of 10 CFR Part 21. This would, for example, remove the manufacturer/distributor of commercial grade stainless steel bar stock from the scope of 10 CFR Part 21 even though that bar stock was subsequently machined into a valve stem and incorporated into a safety-related valve. Such items would come within the scope of 10 CFR Part 21 at the time the item was dedicated to a nuclear application as a basic component. After the dedication, the organization accomplishing the dedication and all other organizations in the procurement chain including the licensee would be required to comply with the current provisions of 10 CFR Part 21, e.g., adopt procedures to evaluate deviations or inform the purchaser of the existence of the deviation, and notify NRC of defects. For example, the valve stem of an ASME Section III Class 2 valve may be identical to the valve stem in a valve being used in the petrochemical industry. The valve manufacturer, who machines the stem from bar stock, would not have informed the bar stock supplier that 10 CFR Part 21 was applicable. At the time the valve stem is withdrawn from the shop stores and incorporated into the nuclear valve, 10 CFR Part 21 would then begin to apply since the bar stock has become a basic component. This alternative will allow the manufacturer of commercial grade items to process all orders for identical items in an identical manner.

Alternative 1:

Maintain the effective 10 CFR Part 21 as it relates to nonlicensee suppliers of "commercial grade items."

- Pro: 1. This is the status quo and as such complies with Section 206 of the Energy Reorganization Act of 1974 as amended.
2. The problems that are being encountered in the implementation of 10 CFR Part 21 may be considered to be associated with the "learning" of a new regulation, i.e., industry may find a way to properly and appropriately implement 10 CFR Part 21.

- Con: 1. Application of 10 CFR Part 21 is causing an adverse effect on the ability to obtain needed items and may increase the costs of such items.
2. Continued application may have an undesired effect on the level of safety presently existing at nuclear facilities and activities because of either the inability to obtain required parts and equipment from the most qualified supplier or the uncertainty as to whether a new supplier who professes to comply with 10 CFR Part 21 is competent to provide the item.
3. Continued application of 10 CFR Part 21 in its present form may cause required supplies to be unavailable and thereby reduce nuclear power plant availability.

Alternative 2:

Amend 10 CFR Part 21 to remove from its scope the nonlicensee suppliers of commercial grade items for any facility or activity that is licensed or otherwise regulated by NRC.

- Pro: 1. The revised rule will remove some impractical portions of 10 CFR Part 21 that are causing cost increases and outright inability to obtain needed supplies without any demonstrable improvement in safety.
2. The revised rule will comply with Section 206 of the Energy Reorganization Act of 1974 as amended.
3. The revised rule, in exempting the suppliers of commercial grade items from the 10 CFR Part 21 regulation, will reduce the potential number of NRC inspections and result in less demand for currently nonexistent NRC inspection resources.

- Con: 1. The revised rule will allow an organization, e.g., a licensee, to procure a "commercial grade item" without the imposition of the 10 CFR Part 21 requirements until after receipt of the item even though the organization has knowledge that the item will be used in a safety-related application.
2. The revised rule will narrow the scope of the NRC inspection authority based on 10 CFR Part 21. However, NRC will retain the authority to inspect suppliers of commercial grade items provided by Subsection 206(d) where reasonably necessary to aid in the identification by the Commission of defects and noncompliances reportable by licensees and suppliers of basic components as provided in 10 CFR Part 21.

Effectivity: If alternative 2 is accepted by the Commission then a decision must be made with regard to when the rule will be effective. The two options described below are believed to be the most viable approaches to rulemaking in this matter.

- A. Effective on publication in the Federal Register and
- B. Publish in the Federal Register a proposal for comment. Following receipt of comments, accomplish comment resolution and publish an effective rule.

Factors to be considered in making this decision involve (a) does the rule comport with the intent of the Commission when the initial rule was approved, (b) the urgency of need of the nuclear industry for this clarifying amendment, (c) method of addressing further comment on this clarifying amendment and (d) the effect upon NRC resources of each course of action.

The Staff believes, and OPE agrees, (see Enclosure 3) that the amendment does comport with the perceived intent in Congress, the discussions between the Commission and the Staff during development of the currently effective 10 CFR Part 21 and the Commission action on the staff recommendations. A number of licensees have requested exemptions (see Enclosure 4) and the Staff believes that a significant number of exemptions have not been submitted since the Staff has stated that it is proceeding on an urgent basis with a

recommendation to the Commission for rulemaking relating to the applicability of 10 CFR Part 21 to the non-licensees' sub-tier suppliers. If the rule is published as a proposed rule the Staff believes that these requests will be submitted. Additional comments from the public or the industry on the amended rule, if published in the effective form, will be addressed as the Staff does all comments on an effective rule.

Enclosure 4 contains the status of the 10 CFR Part 21 exemptions that related to the sub-tier supplier problem as of August 1, 1978. Pending an effective rule change NRC would continue to act on a case-by-case basis on each exemption request in accordance with 10 CFR § 21.7. It will be at least 5 months after the Commission's decision on this paper until a rule change becomes effective in this matter. NRR estimates that six man-weeks (0.12 man years) is required to process an exemption. If NRR is required to act on only 13 exemptions - a conservative number - in the 5 month period it will require 1.56 man-years. A reprogramming of NRR resources would be necessary to accomplish this review of exemptions if option 2B is utilized. No reprogramming would be necessary in relation to the sub-tier supplier problem if option 2A is utilized.

Recommendation:

That the Commission:

1. Approve publication in the Federal Register in effective form of the amendments to Part 21 that are set forth in Enclosure 5. This would remove from the scope of 10 CFR Part 21 organizations that are nonlicensee suppliers of commercial grade items. This is alternative 2.
2. Note:
 - a. The amendments of 10 CFR Part 21 as set forth in Enclosure 5 will be published in the Federal Register to be effective upon publication.

- b. No environmental impact statement, negative declaration, or environmental impact appraisal need be prepared in connection with the amendments because the action taken by the amendments will not significantly affect the quality of the human environment.
- c. A public announcement such as Enclosure 6, which was prepared by the Office of Public Affairs, will be issued when a notice of rulemaking is filed with the Office of the Federal Register.
- d. The Subcommittee on Energy and the Environment of the House Committee on Interior and Insular Affairs, the Subcommittee on Energy and Power of the House Committee on Interstate and Foreign Commerce, and the Subcommittee on Nuclear Regulation of the Senate Committee on Environment and Public Works will be informed by letter such as Enclosure 7.
- e. The proposed action will not require any additional Commission resources.
- f. The proposed action will result in no additional reporting burden on the public or the NRC.
- g. At this time a revision to NUREG 0302³ will not be prepared but in order to give wide distribution to these amendments, a copy of the Federal Register notice (Enclosure 5) will be distributed through the Office of Administration to at least the following:
 - (1) Individuals or organizations identified by IE that received a copy of NUREG 0302 Rev. 1 as a result of attendance at the public regional meetings on Part 21,
 - (2) Individuals or organizations identified by SD that submitted a letter to NRC concerning the proposed or final rule, and

³NUREG 0302 Revision 1, "Remarks Presented (Questions/Answers) Discussed at the Public Regional Meetings to Discuss Regulation (10 CFR Part 21) for Reporting Defects and Noncompliance."

(3) Past and future purchasers of NUREG 0302.

Coordination:

The Offices of IE, NRR, and NMSS concur in the recommendation. The Office of the ELD has no legal objections. Comments of the Office of PE dated August 28, 1978, are contained in Enclosure 3. Comments of the GC dated August 24, 1978, are contained in Enclosure 8. Revisions have been made in the paper, enclosure 4 and 5, in response to the OGC comments.

Scheduling:

Affirmation at an open meeting.

Robert B. Minogue

Robert B. Minogue, Director
Office of Standards Development

Enclosures:

1. Background with Three Attachments
2. Extract from 10 CFR Part 21
3. OPE comments of Aug 28, 1978
4. Status of 10 CFR Part 21 Exemption requests and Exemption requests related to the Sub-tier supplier problem
5. Federal Register Notice
6. Draft Public Announcement
7. Draft Congressional Letter
8. OGC Memorandum of August 24, 1978

Commissioners' comments or consent should be provided directly to the Office of the Secretary by c.o.b. Thursday, September 21, 1978.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT September 15, 1978, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for consideration at an Open Meeting during the Week of September 25th. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

DISTRIBUTION

Commissioners
Commission Staff Offices
Exec. Dir. for Ops.
Regional Offices
Secretariat

BACKGROUND

10 CFR Part 21 was issued to implement Section 206 of the Energy Reorganization Act of 1974. Section 206 states:

"Sec. 206. (a) 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 pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity--

(1) 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

(2) Contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate,

shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

(b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

(d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section."

Implementation of Section 206 as it relates to nonlicensee suppliers was discussed with the Commission on June 18, 1975, and was addressed in

SECY-76-82, and SECY-76-82A.¹ 10 CFR Part 21 was published as a proposed rule on March 3, 1975, at 40 FR 8832. Approximately 140 letters of comment were received. Attachment A contains some of the pertinent comments received at the proposed rule stage relating to the suppliers of "commercial grade items."

A major issue that the Staff presented to the Commission for their action was "How should the Commission define a "basic component"; i.e., how far down the tiers of suppliers should 10 CFR Part 21 be applied?". Enclosure 2, an extract of definitions from 10 CFR Part 21, shows the resolution of this issue. To facilitate implementation of 10 CFR Part 21 throughout the procurement chain (1) five public regional meetings were held in July 1977, (2) staff guidance relating to the implementation and enforcement of 10 CFR Part 21 was published as NUREG-0302 Revision 1² in October 1977, and (3) portions of 10 CFR Part 21 became effective in August 1977, and the remaining portions became effective in January 1978.

After 10 CFR Part 21 became fully effective there have been a significant number of letters, telephone conversations, and meetings concerning the applicability of 10 CFR Part 21 to nonlicensee suppliers of "commercial grade items." The organizations affected by the application of 10 CFR Part 21 have stated that, as presently applied to commercial grade items, (1) the implementation is not practical and effective, (2) compliance with 10 CFR Part 21 may result in a degradation of safety, (3) compliance may result in increased costs without an identifiable increase in safety, and because licensees are unable to procure supplies power plant availability may be reduced due to implementation of Part 21. Attachment B contains some pertinent comments from letters on this subject.

¹This issue is mentioned in the following locations of the SECY papers: SECY-76-82 Encl. A, p. 9-11 in Issue 4, Encl. B, p. 5 in paragraph E3, Encl. F, p. 2 in Issue 4, Encl. F, p. 4 of OGC memo in Issue 4; SECY-76-82A p. 3 in Issue 4, Encl. 3, p. 7-9 in Issue 4.

²NUREG 0302 Revision 1, "Remarks Presented (Questions/Answers) Discussed at the Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting Defects and Noncompliance."

Extracts from letters of
Comment on Proposed 10 CFR Part 21

"The definition of a basic component in Section 21.3(a) is inconsistent with the Act and is too broad to be workable. ... The proposed definition could be interpreted as meaning any portion of or item in a plant. ... It would be much simpler, without losing the force of the Act, to simply keep the definition at the system level, where analyses are made regarding the safety implications of possible defects. ... We therefore recommend that the regulation specifically limit the reporting obligation to responsible officers of applicants, licensees and suppliers contracting directly with an applicant or licensee..."⁽¹⁾

"Our comment relates to the difficulty of the supplier of a 'constituent part' differentiating between a part which he manufactures being used for non-nuclear construction, replacement or nuclear construction falling within the meaning of the Part 21. He may choose to withdraw items of his manufacturer from the market for nuclear components as the alternate for providing more complete inspection programs."⁽²⁾

"...since many such components would be quite inexpensive, many suppliers may not consider the risk to be commensurate with the profit from the transaction and thus discontinue their participation in the nuclear business."⁽³⁾

"The definition of 'basic components' gets undue breadth from the phrase 'system or constituent part.' There seems to be no warrant in the statute for 'constituent part,' and if it is retained it certainly must be confined in some fashion to industrial products which are 'nuclear' in nature."⁽⁴⁾

- (1) W. M. Vannoy, Group Vice President, Babcock & Wilcox, dated April 30, 1975. Letter 33* p 3 & 4.
- (2) W. J. Shelley, Director Regulation & Control, Kerr-McGee Nuclear Corp., dated May 1, 1975. Letter 55 p 2.
- (3) Robert E. Uhrig, Vice President, Florida Power and Light Company, dated May 2, 1975. Letter 60 p 2.
- (4) James P. Hogan, Attorney, General Atomic Company, dated April 30, 1975. Letter 95 Enclosure p 3.

* Letter sequence number assigned by SECY in the docket file for proposed rule making (40 FR 8832).

Extracts from letters of
Comment on Effective
10 CFR Part 21

"We have indications that a number of reliable suppliers whose nuclear business is a small fraction of their total business are resisting the acceptance of Part 21, and industry might lose the services of these companies if there is no relief from these requirements." (1)

"We are finding that when we put 10 CFR, Part 21 on our purchase orders for stock that the pipe mills and fittings manufacturers are adding a further markup to their price levels." (2)

"...we have encountered refusal to furnish materials or sub-components due to the applicability of 10 CFR Part 21... . Continued rejection by suppliers will incur added costs and seriously impact our project schedules. Prompt resolution by the NRC of the extent to which Part 21 is applicable to sub-tier suppliers is necessary if the electric power industry is to avoid severe economic impacts." (3)

"...it appears to us to be unreasonable to require that the provisions of 10 CFR 21 be applied to peripheral areas not directly related to nuclear end use." (4)

"We have thus far declined... (to affirm that we would comply with 10 CFR Part 21 where items in question were purchased from warehouse stock)... because we believe that parts which can be so ordered would not meet the definition of basic components... ." (5)

"where orders are placed 'subject to the provisions of 10 CFR 21' at low levels in the supply chain, there simply is no good business reason to accept them. ...the regulation presents an industry-wide (electrical manufacturing industry) problem.... The solution is nothing short of revision to the regulations which would exclude the supplier (regardless of tier level) where this product/component is a standard component." (6)

- (1) John W. Gore, Jr., Chairman, Committee on Power Plant Design, Construction and Operation, Atomic Industrial Forum, to Dr. Ernst Volgenau, April 6, 1978.
- (2) K. B. Anderson, Vice President and Director of Operations, ITT Grinnell Industrial Piping, Inc. to M. Peranich, IE, April 25, 1978.
- (3) H. O. Reinsch, President, Bechtel Power Corporation to L.V. Gossick, EDO, May 4, 1978.
- (4) Charles Hansen, Executive Vice President, Cutler-Hammer to H. K. Shapar, ELD, May 9, 1978.
- (5) R. O. Hunt, Director of Quality Assurance, Walworth Company, to W. E. Campbell, Jr., March 31, 1978.
- (6) Bernard H. Falk, President, National Electrical Manufacturer's Association to Lee V. Gossick, July 7, 1978. Underscore added.

Attachment B
to Enclosure 1

"The requested exemption will not increase the probability or the consequences of accidents and will not decrease safety margins, it does not, therefore, involve a significant hazards consideration. In this regard, we point out that the enhancement of safety to which 10 CFR 21 is directed will not be substantially changed under the exemption requested." (7)

(7) James F. Young, Vice President-Technical Resources, General Electric Company to Secretary, NRC, June 8, 1978.

Organizations Known to Have Concerns Regarding
Implementation of 10 CFR Part 21 in Regard to
Commercial Grade Item

Sigma International Instruments (instrumentation)¹
General Electric Company (other than nuclear energy division)^{1,3}
Walworth Company (valve)¹
GETE, Sylvania (instrumentation)²
Air Pax (instrumentation)²
Gimpel Machine Works (valve)²
Kingsbury (thrust bearing)²
Tuthill (oil pumps)²
Westinghouse (instrumentation)²
Foxboro (instrumentation)²
Fisher & Porter (instrumentation)³
Allen Bradley (switch gear)³
Elgar Corporation (power supplies)³
Hoffman Engineering (instrumentation cabinets)³
Baldwin Steel³
Buchanan Company (terminal blocks)³
DeLaval Turbine^{3,4}
Bailey Meter^{3,4}
Air Products^{3,4}
PX Engineering^{3,4}
Dravo^{3,4}

¹ Source of information is a direct letter from the organization.

² Source of information is by telephone call from a higher tier purchaser than the organization involved.

³ Source of information is by letter from a higher tier purchaser other than the organization involved.

⁴ Possible cost impact was specifically identified.

Extract from
10 CFR Part 21

§ 21.3(a) "Basic component," when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) 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. "Basic component," when applied to other facilities and when applied to other activities licensed pursuant to Parts 30, 40, 50, 70 or 71 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 § 31.3(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)). In all cases "basic component" includes design, inspection, testing, or consulting services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others.

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

§ 21.3(g) "Evaluation" means the process accomplished by or for a licensee to determine whether a particular deviation could create a substantial safety hazard.

§ 21.3(k) "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, 70 and 71.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

August 28, 1978

MEMORANDUM FOR: Tom Rehm
FROM: Ken Pedersen
SUBJECT: DRAFT STAFF PAPER ON PART 21

I have reviewed the draft paper and have no comments. However, in regard to OGC's memo to you of August 24, I concur in the staff's recommendation that the rule change be made immediately effective. I believe the staff's records will demonstrate that this course of action reflects the sense of the Commission when it approved originally the publication of Part 21 in effective form.

cc: Jim Kelley

CONTACT: Al Konneke, OPE
634-3295
or
Pat Comella, OPE
634-3295

Enclosure 3

10 CFR PART 21 EXEMPTION REQUESTS
RELATED TO SUBTIER SUPPLIERS

<u>Organization</u>	<u>Request Date</u>	<u>Status</u>
NUS via Shaw, Pitman, Potts & Trowbridge	01/05/78	Denied
Philadelphia Electric (50-277 & 278, Peach Bottom 2 & 3) via Connor, Moore & Corber	03/22/78	Granted NRR 04/27/78
Energy Incorporated	03/26/78	Denied EDO 05/30/78
Public Service Company of Colo- rado (50-267 Ft. St. Vrain)	04/11/78	1
Gould, Inc., Switchgear, Division	05/01/78	Denied EDO 08/04/78
General Electric - Fairfield	06/08/78	Denied EDO 06/30/78
Ohama Public Power District (50-285, Ft. Calhoun Station #1) via LeBoeuf, Lamb, Leiby & MacRae)	06/14/77	1
C-E Power Systems	07/07/78	Denied SD 08/22/78
SNUPPS (50-482 through 486)	07/21/78	1
Baltimore Gas & Electric Company (Calvert Cliffs)	07/25/78	1
Virginia Electric & Power Co. (50-280, 281 Surry 1 & 2)	07/25/78	1
Louisiana Power and Light (50-382 Waterford 3)	07/28/78	1
Public Service Electric & Gas (50-272, 311 Salem 1 & 2)	07/31/78	1

¹ Pending at NRR.

Title 10 - Energy

CHAPTER I - NUCLEAR REGULATORY COMMISSION

Part 21 - Reporting of Defects and Noncompliance

Amendments Regarding Basic Component

AGENCY: Nuclear Regulatory Commission

ACTION: Final Rule

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to limit the types of items that are within the scope of its rule for reporting defects and noncompliance. This action is believed necessary since the currently effective rule is being applied by organizations within its scope to an extent not contemplated and is causing problems relating to the supplying of equipment. The amendments provide that items that are available in general commerce and which have no unique requirements imposed for nuclear application will not be within the scope of the revised rule for reporting defects and noncompliance. These amendments will alleviate the above problem.

DATE: These amendments will be effective on [the date of noticing in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Mr. W. E. Campbell, Jr., Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, 301-443-5913.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Nuclear Regulatory Commission (hereinafter the "Commission") has decided to amend 10 CFR Part 21 "Reporting of Defects and Noncompliance." Specifically, the Commission has decided to impose limits on the types of items that are used in facilities or activities licensed pursuant to Parts 30, 40, 50, 70, or 71 that are within the scope of 10 CFR Part 21.

On March 3, 1975, 10 CFR Part 21 was published as a proposed rule (40 FR 8832). On June 6, 1977, 10 CFR Part 21 was published as an effective rule (42 FR 28891) with some portions of the rule to be effective on July 6, 1977, and the remaining portions to be effective on January 6, 1978. On July 7, 1977, a Federal Register notice (42 FR 34886) changed the initial effective date to August 10, 1977 vice July 6, 1977. To facilitate implementation of 10 CFR Part 21 a series of public regional meetings were held in July 1977 and based on those meetings the Commission Staff in October 1977 published NUREG-0302 Rev. 1, "Remarks Presented (Questions/Answers) Discussed at the Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting Defects and Noncompliance." NUREG-0302 Rev. 1 contains staff guidance relating to the implementation and enforcement of 10 CFR Part 21 and is available through the National Technical Information Service, Springfield, Virginia, 22161. In the preamble to the effective rule, the Commission stated that it intended "to examine closely the implementation of 10 CFR Part 21 with a view

to making any clarifying or other changes that may be warranted in the light of experience."

Part 21 defines a "basic component" subject to the reporting and other requirements of the rule. In response to inquiries during and subsequent to the public regional meetings relating to "off-the-shelf" or "catalog" items, the staff provided guidance that such items may be within the scope of 10 CFR Part 21 depending on the circumstances at the time of procurement. This guidance has been construed by numerous organizations to mean that the requirements of 10 CFR Part 21 apply to manufacturers and distributors who are involved to any extent in supplying basic components, or parts of basic components, of a facility or activity including supplying base material or functional assemblies to the manufacturer of the "basic component." This meaning has lead to the imposition of 10 CFR Part 21 at a procurement stage where there are no design or specification requirements that are unique to application of the item at a nuclear facility or activity, e.g., relays.

The use of this meaning of basic component has not improved the quality of such items and, therefore, has not enhanced safety. Instead it is causing cost increases, and inability to obtain needed supplies. To the extent that the purchaser is unable to obtain a needed item from the most qualified supplier and must turn to other less qualified suppliers, defining basic component to include such an item may to some extent detract from safety. To relieve the conditions that are resulting from the above interpretation and to mitigate this potential

reduction of safety Part 21 is being amended to remove from the scope of 10 CFR Part 21, during specific stages of procurement, those items of a commercial grade, e.g., bearings, relays, and bar stock that are (1) not subject to design or specification requirements unique to facilities or activities licensed by the Commission, (2) used in applications other than facilities or activities licensed by the Commission and (3) able to be ordered from the manufacturer/distributor on the basis of the manufacturer's published specifications. At a defined stage of procurement, when the item is "dedicated" to a "basic component" (see 10 CFR 21.3(c-1)) the item will become subject to the requirements of 10 CFR Part 21.

Prior to these amendments 10 CFR Part 21 included within its scope direct inspections of licensees and suppliers as provided under Section 206 of the Energy Reorganization Act of 1974. The revised rule will narrow the scope of the NRC inspection authority based on 10 CFR Part 21. However, NRC will retain the authority to inspect suppliers of commercial grade items provided by Subsection 206(d) where reasonably necessary to aid in the identification by the Commission of defects and noncompliance reportable by licensees and suppliers of basic components as provided in 10 CFR Part 21.

Procurement documents that were issued in accordance with 10 CFR § 21.31 after August 10, 1977, and invoked 10 CFR Part 21 may be amended to delete reference to 10 CFR Part 21 if the item being procured complies with the definition of a "commercial grade item" (see 10 CFR 21.3(a-1)).

The amended rule will clarify the applicability of 10 CFR Part 21 and thereby allow for precise application of the rule to those items that

are subject to design or specification requirements unique to facilities or activities licensed pursuant to parts 30, 40, 50, 60 or 71 or 10 CFR Chapter 1.

Since the amendments are intended, in part, to respond to a number of requests for exemptions from 10 CFR Part 21 which are necessary to ensure the continued availability of components for the nuclear industry and since the amendments narrow the scope of the regulation thereby relieving a restriction on persons subject to it, the Commission has found that good cause exists for omitting notice of proposed rulemaking and public procedure thereon as contrary to the public interest, and the Commission has further found that the amendments should be made effective upon publication in the FEDERAL REGISTER without the customary notice period.

* * * * *

1. The final sentence of § 21.2 is amended to read as follows:
Nothing in these regulations should be deemed to preclude either an individual or a manufacturer/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. ^[2] 1

2. A new sentence is added to the end of § 21.3(a) to read as follows:
A commercial grade item is not a part of a basic component until after dedication. (see § 21.3(c-1)).

3. New paragraphs (a-1) and (c-1) are added to § 21.3 to read as follows:

(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, 70, or 71 of this chapter and (2) used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 70, or 71 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).

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

4. A new sentence is added to the end of § 21.7.

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

* * * * *

Sec. 161, Pub. L. 83-703, 68 Stat. 948; sec. 234, Pub. L. 91-161, 83 Stat. 444; sec. 206, Pub. L. 93-438, 88 Stat. 1246 (42 USC 2201, 2282, 5846).

Dated at Washington, D.C., this _____ day of
August 1978.

For the Nuclear Regulatory Commission.

NRC AMENDS REGULATION ON REPORTING DEFECTS IN
COMPONENTS OF NUCLEAR FACILITIES

The Nuclear Regulatory Commission is eliminating commercial grade items from the scope of its regulation on reporting defects in basic components for nuclear facilities.

Part 21 of NRC regulations requires directors and responsible officers of firms or organizations building, operating or owning NRC-licensed facilities or conducting NRC-licensed activities, to report defects in components and failures to comply with regulatory requirements which may result in a substantial safety hazard. Also covered are directors and responsible officers of firms supplying safety-related components and safety related design, testing, inspection and consulting services. The covered firms must adopt internal procedures to implement the regulation. Failure to comply with the reporting requirements can result in civil penalties.

Interpretations of "basic component" under which Part 21 has been applied to commercial grade or "off-the shelf" items have resulted in difficulties obtaining needed items or obtaining them at increased prices. Continued application may have an undesired effect on the level of safety existing at facilities because of the inability to obtain needed items.

To relieve these conditions, Part 21 is being amended to limit its scope to include licensees and organizations supplying basic components which are not commercial grade items. This would, for example, remove the manufacturer/distributor of a commercial grade steel bar stock from the scope of Part 21 even though that bar stock may subsequently be used in a

safety-related nuclear valve. That item would become a basic component when its purchaser determines that it will in fact be a part of a nuclear component. At that point, Part 21 would apply.

The amendment to Part 21 is effective upon publication in the Federal Register on _____.

DRAFT CONGRESSIONAL LETTER

Enclosed for the information of the Subcommittee are copies of a Notice of Rule Making to be published in the Federal Register.

The amendment of Title 10, Code of Federal Regulations, Chapter I, Part 21, "Reporting of Defects and Noncompliance" responds to a number of requests for exemptions from 10 CFR Part 21. The currently effective rule is being applied by organizations within its scope to an extent not contemplated and is causing problems relating to the supplying of equipment.

Continued application of the currently effective rule may have an undesired effect on the level of safety presently existing at nuclear facilities and activities, because of either 1) the inability to obtain required parts and equipment from the most qualified supplier or 2) the uncertainty as to whether a new supplier, who professes to comply with the currently effective rule, is competent to provide the item.

These amendments provide that items, that are available in general commerce and which have no unique requirements imposed for nuclear application, will not be within the scope of the revised rule.

Also enclosed is a copy of a public announcement to be released by the Commission on this matter in the next few days.

Sincerely,



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

August 24, 1978

MEMORANDUM FOR:

Thomas A. Rehm
Assistant to the EDO

FROM:

Stephen F. Eilperin
Acting General Counsel

SUBJECT:

OGC COMMENTS ON DRAFT STAFF PAPER
ON AMENDMENTS TO PART 21

This draft staff paper is concerned with amendments to Part 21 to exempt commercial materials and parts from NRC reporting regulations. We understand that the ambiguity in Part 21 has caused serious problems for licensees and their suppliers. The proposed solution to the problem consists of narrowing the scope of the regulations to exempt certain commercial materials in a final rule to be made immediately effective. While we believe that there may be a strong factual basis for this course of action, we are not convinced that that case has been made in the paper and in the proposed Federal Register notice to indicate to the public that "good cause" exists to permit NRC to exempt this rule from the notice and comment requirements of the Administrative Procedure Act. 5 U.S.C. 553(b). Because Part 21 has attracted so much attention in the past, it is likely that some members of the public would have an interest in commenting on this amendment. In order to minimize any risks in claiming the exemption under the Administrative Procedure Act, we strongly recommend that the rule set forth clearly the factual basis for the NRC claim that good cause exists for making a final rule immediately effective without prior notice to the general public and solicitation of public comment.

Finally, we recommend that another alternative be considered to an immediately effective final rule. If there is a need for swift NRC action in certain hardship cases, the NRC could

Contact:
Mark E. Chopko, OGC
634-1465

Enclosure 8

Thomas A. Rehm

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August 24, 1978

grant exemptions on a case-by-case basis while soliciting comment on the amendment to Part 21. This method would have the advantages of providing relief to those who need it while at the same time affording public comment prior to a more general rule change.

cc: K. Pedersen, OPE

Enclosure 8

10 CFR PART 21 APPLICABILITY TO NON LICENSEE
SUPPLIERS OF COMMERCIAL GRADE ITEMS
(SECY 78-496)

- PURPOSE:
- 1) INFORM THE COMMISSION OF THE IMPACT OF 10 CFR PART 21
 - 2) SEEK COMMISSION APPROVAL OF A NOTICE OF RULEMAKING
- BACKGROUND:
- 1) ENERGY REORGANIZATION ACT OF 1974 §206
 - 2) 10 CFR PART 21 (42 FR 28891/JUNE 6, 1977)
- PROBLEM:
- IMPLEMENTATION AS INTENDED IN A PRACTICAL AND EFFECTIVE MANNER
- RECOMMENDATION:
- 1) RULE CHANGE
 - 2) TIMING

PL 93-438 § 206

- a) Any . . . Director, or Responsible Officer . . .
Shall . . . Notify the Commission of Such . . .
Defect . . .

PL 93-438 § 206 (CONT.)

b) Any Person Who . . . Shall be Subject to a
Civil Penalty . . .

PL 93-438 § 206 (CONT.)

- d) The Commission is Authorized to Conduct
Such Reasonable Inspections and Other
Enforcement Activities...

IMPLEMENTING PROVISIONS (CONT.)

21.31 Each . . . Entity . . . Shall Assure
That Each Procurement
Document . . . Specifies
10 CFR Part 21 . . .

§21.3

(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, 70, OR 71 OF THIS CHAPTER AND (2) USED IN APPLICATIONS OTHER THAN FACILITIES OR ACTIVITIES LICENSED PURSUANT TO PARTS 30, 40, 50, 70, OR 71 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).

821.3

(c-1) "DEDICATION" OF A COMMERCIAL GRADE ITEM OCCURS AFTER RECEIPT WHEN THAT ITEM
IS DESIGNATED FOR USE AS A BASIC COMPONENT.

8270-2

§21.3 DEFINITIONS

"..." BASIC COMPONENT, "WHEN APPLIED...MEANS.... ...A COMMERCIAL GRADE ITEM IS NOT A PART OF A BASIC COMPONENT UNTIL AFTER DEDICATION. (SEE §21.3(c-1))."

§21.2 SCOPE

"...NOTHING IN THESE REGULATIONS SHOULD BE DEEMED TO PRECLUDE EITHER AN INDIVIDUAL OR A MANUFACTURER/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. {2} 1"

§21.7 EXEMPTIONS

"THE COMMISSION MAY...GRANT SUCH EXEMPTIONS.... SUPPLIERS OF COMMERCIAL GRADE ITEMS ARE EXEMPT FROM THE PROVISIONS OF THIS PART TO THE EXTENT THAT THEY SUPPLY COMMERCIAL GRADE ITEMS."