UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
GENERAL COUNSEL

February 5, 2003

Mark Kulwich
235 Hartland Road
West Granby, CT 06090

Dear Mr. Kulwich:

I am responding on behalf of the General Counsel, Karen D. Cyr, to your November 20, 2002, letter requesting a clarification of the "intent" of 10 CFR 21.21. I would like to preface my response by pointing out that the Commission's regulations authorize the General Counsel to issue formal, written interpretations of laws, regulations, and other sources of guidance, which are recognized as binding on the Commission and codified in 10 CFR Part 8 of the Commission's regulations. However, the General Counsel exercises this authority very sparingly and only in instances involving major policy or legal questions. Accordingly, the views in this letter do not constitute a formal interpretation. My response is intended to provide you with this office's perspective regarding the meaning of the provisions of 10 CFR 21.21 relevant to the issues you raise in your letter.

Your letter requests clarification of 10 CFR 21.21 with regard to the following three issues: (1) whether 10 CFR 21.21 excludes reporting of a condition which has been remedied at the time that the substantial safety hazards determination is made; (2) whether 10 CFR 21.21 excludes reporting of a condition which is limited to a particular plant or class of plants; (3) whether, if the particular condition is limited to a particular plant or class of plants, it is necessary to address the extent of condition that could occur if the condition were not corrected. In your letter, you describe a situation involving a "no significant hazards" determination made by a vendor which you believe was flawed and which has led you to raise these issues. Among other things, you indicate in your letter that the vendor, Westinghouse Electric Company, performed an evaluation of a failure to perform adequate maintenance of safety systems and inappropriately concluded that since the isolated condition leading to the failure had been corrected and was limited to a particular plant, it did not constitute a reportable defect.

10 CFR 21.21(a) provides in part that entities subject to Part 21 must adopt appropriate procedures to (1) evaluate deviations to identify defects associated with substantial safety hazards 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. 10 CFR 21.21(d)(1) provides further that a director or responsible officer must notify the Commission within two days upon obtaining information reasonably indicating a defect affecting (i) the construction or operation of a facility or activity that is subject to certain licensing requirements and 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 subject to those licensing requirements. "Defect" is defined in 10 CFR 21.3 in part as (1) a deviation in a basic component that, on the basis of an evaluation, could create a substantial safety hazard; (2) the installation, use or operation of a basic component containing a defect; (3) a deviation in a

portion of a facility offered to a purchaser for acceptance that could on the basis of an evaluation create a substantial safety hazard; or (4) a condition involving a basic component that could contribute to the exceeding of a safety limit as defined in license technical specifications.

Neither the regulations in Part 21, the Statements of Consideration (Statements) which accompanied the rule when it was implemented in 1977, nor the Statements explaining the extensive amendments to the rule made in 1991 directly address the issue which you appear to be raising as to whether the need to report a defect to the Commission is negated by the fact that the evaluating entity has corrected the defect and/or made a determination that this defect could not affect other facilities. Nor do the regulations or the Statements specify how the evaluation must be completed or what must be included in the evaluation.

As noted in the Statements which accompanied the regulation when it was first published, 42 FR. 28891 (June 6, 1977), the purpose of the regulation was to implement Section 206 of the Energy Reorganization Act of 1974, as amended. That statute provides in part that any individual director, or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity regulated under the Atomic Energy Act who obtains information reasonably indicating that it contains a defect which could create a substantial safety hazard, as defined by regulations to be promulgated by the Commission, immediately notify the Commission. The legislative history behind Section 206 indicates that the section was promulgated because of an imperative need for information by the Commission relating to nuclear defects, and, as the Statements relate, as a result of an identification by Congress for an effective means to "anticipate problems before the event." The Statements further note that the regulations being promulgated in Part 21 added another required notification to those already in existence, and that such communications were methods of securing information which were "an essential ingredient of sound regulation."

10 CFR 21.21(a) originally provided that entities subject to the regulations were to adopt procedures to: (1) provide for (i)evaluating deviations or (ii)informing the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated, "unless the deviation has been corrected," and (2) assure that a director or responsible officer be informed if there was a defect. The language of 10 CFR 21.21 (b) was essentially the same as that now in section 21.21(d), insofar that it provided for notification by the director of the Commission when he obtained information reasonably indicating a defect. However, the rule did not specify a time period for completing the evaluation of the potential defect or for notifying a director or responsible officer of a potentially reportable defect.

In 1991, the Commission amended its regulations in Part 21 (56 FR 36081 (July 31, 1991)). As noted in the Statements, the amendments partly resulted from Commission efforts to apply the experience gained as a result of the Three Mile Island (TMI) event and from a TMI Action Plan mandate that the NRC staff evaluate and revise the existing requirements to assure prompt and comprehensive reporting. Other Commission regulations contained similar reporting requirements, and the changes were geared to reduce duplicate reporting of defects, clarify the criteria for reporting defects, and establish uniform time periods for reporting and uniform requirements for the content of safety defect reports.

As further explained in the Statements, the changes to the rule to establish time limits for evaluating defects resulted from Commission concern over cases in which an inordinate length of time had passed between the discovery of a potential defect and notification of the Commission. Noting that Section 206 of the ERA mandated immediate notification to the Commission of defects, the Statements explained that the Part 21 had been amended accordingly to require the evaluation of deviations to be completed within 60 days after the date of discovery, and to require that a director or responsible officer be informed within five working days of completion of the evaluation identifying existence of a defect associated with a substantial safety hazard.

In the course of amending the regulations, the language was changed from requiring that the licensee or purchaser of the deviation be informed in order that it may cause the deviation to be evaluated "unless the deviation has been corrected," to the present language that deviations be evaluated "in order to identify a reportable defect or failure to comply that could create a substantial safety hazard were it to remain uncorrected." The Statements do not address the issue of why the language was revised in this way. However, the fact remains that the words as they now are written clearly state that deviations must be evaluated to identify defects that could result in a substantial safety hazard assuming they had remained uncorrected. There is no exception specified in the rule that allows nonreporting of a defect to the Commission if the defect has been corrected. Nor is there any mention of an exception to reporting if the evaluating entity has concluded that the defect will not affect another facility. To the contrary, when the rule was promulgated in 1977, remarks made by William T. Russell, then Project Manager, Office of Nuclear Reactor Regulation, at public meetings held regarding expected Part 21 impacts indicate that it is the NRC that makes that determination during its evaluation of the reported defect. *See* "Remarks by the Office of Nuclear Reactor Regulation to Public Regional Meetings on 10 CFR Part 21 by William T. Russell," NUREG 0302 Rev. 1, p. 3. (copy of remarks attached)

In this connection, there is a long-standing, fundamental cannon of statutory construction that when the words of a statute are unambiguous, there is a presumption that a legislature says in a statute what it means and means in a statute what it says. This same principle has been applied by the NRC in interpreting its regulations; i.e., when the meaning of the regulation is clear, the regulatory language is conclusive and unwarranted meanings may not be read into an unambiguous regulation. Since the regulation does not contain an exception to the reporting requirements for defects that have been corrected or situations in which the evaluating entity assumes that the defect would not affect another facility, we conclude that there is in fact no such exception to the reporting requirement. Such a conclusion is supported by the Statements of Consideration to the rule and the legislative history behind Section 206 of the ERA, which emphasize the unqualified need for the Commission to promptly obtain information indicating the existence of a defect.

Based upon the above discussion, our responses to the specific issues raised in your letter are as follows: (1) 10 CFR 21.21 does not exclude reporting of a condition which has been remedied at the time that the substantial safety hazards determination is made. (2) 10 CFR 21.21 does not exclude reporting of a condition which the evaluating entity believes is limited to a particular plant or class of plants. The evaluating entity may make a determination of whether the condition is limited to a particular plant or class of plants, but this should not form the basis for its reportability determination. Instead, it is the responsibility of the evaluating

entity to report this information to the NRC, so that the NRC can use the information as it deems necessary or appropriate. (3) There are no specific requirements as to how an evaluation must be conducted or the elements that must be considered. However, the regulation provides that the procedures for evaluating the deviations must be appropriate so as to ensure identification of a defect that could create a substantial safety hazard were it to remain uncorrected. Therefore, it seems evident an evaluation would have to consider the extent of the condition that could occur if the condition were not corrected in order to determine whether the extent of the condition could rise to the level of a substantial safety hazard.

In providing this response, we are responding to the general questions that you have asked regarding the interpretation of 10 CFR 21.21. In doing so, we emphasize that we are not making a determination as to whether the specific situation you described in your letter (i.e., the "no significant hazards" determination by Westinghouse and its determination not to report the situation to the NRC) constituted a violation of the Commission's requirements in Part 21. We have referred your letter and the supporting documentation you have provided to the Commission's Office of Nuclear Reactor Regulation for its consideration of this matter. In this regard, we understand the staff has been in contact with Westinghouse for the purpose of gathering the pertinent information regarding this matter.

Sincerely,

Stuart A Treby

Stuart A. Treby
Assistant General Counsel
for Rulemaking & Fuel Cycle

Attachment: As stated

cc: Stephen Alexander

REMARKS BY
THE OFFICE OF NUCLEAR REACTOR REGULATION
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
BY
WILLIAM T. RUSSELL

JULY 12-26, 1977

HOW PART 21 IMPACTS REACTOR LICENSING, LICENSEES AND SUPPLIERS

My name is William Russell and I am a Project Manager in the Office of Nuclear Reactor Regulation's Division of Operating Reactors. My objective is to provide some insight as to the scope of reactor activities to which Part 21 applies, the general criteria that we will be using in our evaluation of reported Part 21 items and how we will factor this information into the reactor licensing process. I will also discuss the impact of this new rule on reactor licensees, vendors, contractors and consultants.

Background

The Energy Reorganization Act of 1974, which established the Nuclear Regulatory Commission, provided a specific review function to include "monitoring, testing and recommending upgrading of systems designed to prevent substantial health or safety hazards." In partial fulfillment of this, NRC reviews operating experience, including reports from NRC inspectors, reactor licensees and vendors. We also review information obtained from NRC research and from foreign exchange agreements. As new technical information and operating experience become available the Office of Nuclear Reactor Regulation determines whether such information could significantly alter previously determined levels of reactor safety. When we conclude that the level of safety has been or may be degraded, timely licensing action is taken. The action taken varies based upon the potential hazard to the public health and safety. These actions can range from an order to shut down a reactor to a request that affected licensees determine the effect of the new technical information or operating experience upon their facilities. Through this process of identifying and resolving technical issues and applying this information to operating reactors, a data base of experience is evolving that is having a positive impact on new plant designs.

Typical Part 21 Report Scenario

The reporting of defects and noncompliance pursuant to 10 CFR Part 21 will be incorporated into the reactor licensing process in a similar manner. A typical scenario for a safety-related defect reported by a basic component supplier for a power reactor facility may start with the discovery that a basic component already furnished by that supplier deviates from the procurement document specifications. The supplier would evaluate the deviation or would report the deviation to the purchaser to allow the purchaser to determine if a substantial safety hazard is involved. It is expected that in most instances the supplier's evaluation would require discussion with the purchaser. If, based upon this evaluation, it is concluded that the deviation could create a substantial safety hazard then the deviation must be reported as a defect to the NRC. Before describing how the NRC evaluates and uses Part 21 reports, I will discuss a substantial safety hazard.

The general criteria which we will use in evaluating a substantial safety hazard are identified in the statement of consideration which was published with the new rule. These criteria include: moderate exposure to, or release of, licensed material; major degradation of essential safety-related equipment; and major deficiencies in design, construction, inspection, test or operation. For a power reactor, Regulatory Guide 1.29, identifies the essential safety-related equipment which must remain functional during the Safe Shutdown Earthquake. These safety-related equipments are necessary to ensure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shutdown the reactor and maintain it in a safe shutdown condition and (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposure comparable to the guideline exposure of 10 CFR Part 100. Under the new rule these essential safety-related equipments are defined as "basic components." Major degradation of such basic components, or a condition or circumstance involving a basic component that could contribute to exceeding a safety limit is considered a substantial safety hazard. In the case of a redundant basic component, a condition, circumstance or deviation which could cause a failure of that component must be evaluated to determine if there maybe a loss of safety function for the affected basic component or a major reduction in the degree of protection provided to public health and safety. Therefore, a defect in a basic component, even though a redundant component exists, could be reportable under Part 21.

The Office of Inspection and Enforcement will perform the initial evaluation of the safety significance of the reported defect or noncompliance and will evaluate the action being taken by the supplier

and licensee. I&E also determines whether an unreviewed safety issue may exist, if a licensing action is required or if inspection or enforcement action is necessary. If a licensing action or unreviewed safety issue is involved, the Office of Nuclear Reactor Regulation (NRR) would be advised and would assume lead responsibility for further NRC action. Within NRR, the Division of Operating Reactors has the responsibility to collect and evaluate experience with operating reactors to assure that appropriate and timely corrective action is taken and to feed back information to other NRR divisions conducting evaluations of proposed reactor facilities. The reported defect is also evaluated to determine if it is common to several reactor facilities. Our review may require the affected reactor licensees to submit additional information and analysis. Interim licensing action may be taken to assure the public health and safety during our review. The interim licensing action could be an order to shutdown, reduce power or other restrictions or conditions on reactor operation pending final resolution of the problem. The final licensing action could require replacement of the defective component or appropriate restrictions on reactor operation. The scenario I have just described is an example of the feedback of reports of defects and noncompliance into reactor licensing.

Impact on Reactor Licensees and Supplier Organizations

I would like to shift gears for a moment to discuss the impact of the new rule on reactor licensees and upon private industry involved in design, construction, test, inspection and consultation for nuclear reactors. For several years we have been requiring permit holders to report significant deficiencies and deviations discovered which could adversely affect the safety of future operation. This reporting is required as a condition of the facility construction permit under 10 CFR 50.55(e). Similarly, the Technical Specifications issued as a part of every power reactor operating license require the reporting of significant failures, malfunctions, degradation and deviations as Licensee Event Reports. Regulatory Guide 1.16 identifies the type of information to be reported in Licensee Event Reports. Therefore, for the power reactor licensee, the notification requirements of the new rule are different only in scope from reporting requirements which are already in place. Duplicate reporting under Part 21 is not required. For example, a Licensee Event Report, which includes all appropriate information required for a Part 21 Notification, would satisfy the requirement that the licensee's director or responsible officer has actual knowledge that the Commission has been adequately informed and a separate Part 21 Notification would not be required. Most research and test reactor licensees are subject to similar reporting requirements as conditions of their construction permits and their operating license Technical Specifications.

The notification of defects and noncompliance which could create a substantial safety hazard is necessary to insure that potential reactor safety hazards are promptly identified, evaluated and resolved. It is for this reason that the notification requirements of Part 21 include organizations supplying safety-related equipment and safety-related services. Safety-related services include design, engineering, testing inspecting and consulting services which could, if they contained defects, create a substantial safety hazard. Examples of these types of safety-related services and software are:

- Nondestructive examination of safety-related welds,
- Design of safety-related pipe hangers and supports,
- Seismic and geologic surveys for a reactor site,
- Specification of safety-related hardware characteristics,
- Computer codes for reactor analysis,
- Emergency procedures, and
- Fire protection inspections by fire consultants

Organizations providing these types of safety-related services, as well as licensees and firms that physically construct facilities or supply basic components, must establish procedures to identify deviations from technical requirements and must provide for evaluations to determine if defects exist. These procedures must also assure that directors and responsible officers are informed of the existence of defects in delivered products. For some organizations the implementation of new internal procedures for evaluation of deviations will not be required to accommodate Part 21. Company procedures for the evaluation of deviations which were previously performed as part of good engineering and management practice may be sufficient. Records in connection with design, manufacture, fabrication, placement, erection, test and inspection of basic components and facilities, sufficient to insure compliance with the new rule shall be maintained. The records required to be kept under the quality assurance programs specified under 10 CFR Part 50 Appendix B should satisfy the record keeping requirements of the new rule.

Tie-In With Safeguards Rule

Before I conclude I would like to address one additional item. When Part 21 was published in the Federal Register, the statement of considerations addressed failures to comply or defects in a security system.

The NRC recently adopted a new regulation which identified additional requirements for the physical security of nuclear power reactors. The primary safeguards concern for nuclear power reactors is for potential acts of sabotage or terrorism. Such acts are of concern because they could lead to the release of significant amounts of radioactive material which could endanger the public health and safety. Therefore, failures to comply or defects in a security system can contribute to the creation of a substantial safety hazard and are within the scope of Part 21. For example, a defect or noncompliance which allows or could allow an unauthorized individual to gain access to a vital area of a nuclear power plant without being detected by means other than visual surveillance, including remote visual-electronic surveillance, is considered to be a substantial safety hazard and is therefore reportable under Part 21.

Conclusion

In conclusion, I have outlined the basic method by which operating experience including reports of defects and noncompliance are reviewed and as appropriate fed back into the licensing process. I have also discussed the impact of the notifications and record keeping requirements of the new rule upon both reactor licensees and others in the nuclear reactor industry. The process of identifying deviations, conducting evaluations and notifying the NRC of substantial safety hazards will require additional effort and some additional costs. However, the long term benefit of being able to anticipate potential safety problems is substantial.