

August 15, 2008

Dr. A.V. Setlur, PE
Automated Engineering Services Corp.
40 Shuman Blvd, Suite 220
Naperville, IL 60563

SUBJECT: RESPONSE TO 10 CFR PART 21 QUESTIONS

Dear Dr. Setlur:

By letter dated June 11, 2008, you requested the U.S. Nuclear Regulatory Commission (NRC) General Counsel's assistance with the interpretation of the rules of 10 CFR Part 21, "Reporting of Defects and Noncompliance." Specifically, you requested a response to two questions regarding a software vendor who believed that 10 CFR Part 21 does not apply to its software product.

Please be advised that, although 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, the General Counsel exercises this authority very sparingly and only in instances involving major policy or legal questions. For this reason, the following is not an interpretation of 10 CFR Part 21 by the NRC's General Council office but a response by the responsible technical staff to your questions.

Question (1):

Does 10 CFR Part 21 apply to software used for safety-related calculation in the Nuclear Power Industry?

Response:

Yes. Under 10 CFR Part 21.2, "Scope", the regulations in 10 CFR Part 21 apply to each entity that supplies basic components for a facility or activity licensed by the NRC. 10 CFR 21.3, "Definitions", defines a basic component as a structure, system, or component, or part thereof that affects its safety function. This includes safety-related design, analysis, inspection, tests, fabrication and replacement of parts or consulting services that are associated with the component hardware. If the software was used for safety-related calculations or as part of the operation of another basic component, the software would be considered a basic component and 10 CFR Part 21 would apply.

Furthermore, NRC document, NUREG-0302, Rev. 1, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance" dated July 12-26, 1977, states the following as part of remarks on how Part 21 impacts reactor licensing, licensees and suppliers:

“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 [emphasis added]** 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 [emphasis added],**

Question (2):

If a vendor accepts 10 CFR 50 Appendix B, is 10 CFR Part 21 included in his acceptance of 10 CFR 50 Appendix B?

Response:

You have stated in your letter that the purchase order in this case stated both that the vendor shall implement a quality assurance program meeting the applicable requirements of 10 CFR Part 50, Appendix B, and that applicable portions of 10 CFR Part 21 reporting is applicable to this purchase order. The purchase order was accepted by the vendor. Therefore, in this case, the requirements of both 10 CFR Part 50 Appendix B and 10 CFR Part 21 are binding upon the vendor.

Should you have any further questions, please contact me, Dale F. Thatcher at 301-415-3260 or Mr. Paul Prescott at 301-415-3026, also from the Quality and Vendor Branch (EQVB) in the office Nuclear Reactor Regulation (NRR).

Sincerely,

/RA/

Dale F. Thatcher, Chief
Quality & Vendor Branch
Division of Engineering
Office of Nuclear Reactor Regulation

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Dale F. Thatcher, Chief
 Quality & Vendor Branch
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 Office of Nuclear Reactor Regulation

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