



March 15, 2012

CD12-0072

Mr. Douglas Weaver
Acting Director, Division of Spent Fuel
Storage and Transportation
Office of Nuclear Materials, Safety, and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: Request for NRC Position on Controls of Type B Package Fabrication

Dear Mr. Weaver:

The purpose of this letter is to obtain the Nuclear Regulatory Commission (NRC) position as to whether a person can fabricate a type B shipping package based on NRC public documents associated with an NRC approved package without the involvement and authorization of the person possessing the NRC-issued Certificate of Compliance (CoC) for the package. As a holder of NRC Certificates of Compliance for type B packages, EnergySolutions desires to understand the NRC position on that matter as well as the regulatory responsibility of the certificate holder.

It is our understanding that under 10 CFR Part 71, the certificate holder is responsible for maintaining the safety and certification approval basis for the package and for ensuring that required design and quality controls are maintained throughout the fabrication process. As such, the certificate holder is subject to NRC inspections and sanctions for non-compliance. We believe that inadequate controls could result if an entity were to fabricate a package without the involvement of the approved package certificate holder, who is, in fact, the designer of record for the package. Such a package would be of indeterminate quality with respect to its design, safety, and certification bases. We have attached to this letter a description of foreseeable problems that can be adverse to the public health and safety if a package were to be fabricated without the involvement and the required controls of the certificate holder.

Accordingly, it is the position of EnergySolutions that 10 CFR Part 71 requires the certificate holder and the package fabricator have an ongoing arrangement that establishes a formal process preserving the certificate holder's control of the package fabrication and design. Under such an arrangement, the fabricator must obtain the certificate holder's fabrication details, e.g., proprietary drawings and specifications, so that the certificate holder can assure that the package has the material and assembly characteristics necessary to preserve the safety, quality, and certification basis. Without such assurance by the certificate holder, a package may not be loaded or shipped by licensees as a certified package. Consequently, it is our view that a person cannot fabricate a Type B shipping package merely based on public documents associated with

an NRC-approved package. Rather, that person must maintain the involvement and authorization of the person possessing the NRC issued CoC for the package.

In light of the potential impact on the public health and safety, *EnergySolutions* requests that the NRC confirm our position as set forth above. If NRC differs with this position, we request that the NRC define a certificate holder's regulatory responsibility if a person uses that certificate holder's design for a certified package without the certificate holder's authorization and involvement. In addition, we request that NRC give consideration to publishing its position in a suitable generic communication in the interest of avoiding misunderstandings in the industry.

If you have any questions on this request, please contact me at (240) 565-6148 or temagette@energysolutions.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas Magette". The signature is written in a cursive style with a large, stylized initial "T".

Thomas E. Magette, P.E.
Senior Vice President
Nuclear Regulatory Strategy

cc: Cathy Haney, NMSS

Potential Problems If a Package Were to be Fabricated Without Involvement of the Certificate of Compliance Holder

Normal situation – An applicant for a Type B Certificate of Compliance (CoC) develops a design of a proposed package. This design meets the requirements in 10 CFR 71¹, and insofar as practicable, follows the guidance in the *Standard Review Plan for Transportation Packages for Radioactive Material* (NUREG-1609). The design would also incorporate the applicable guidance that is contained in Division 7 of NRC Regulatory Guides, relevant Bulletins, Generic Letters, Information Notices, Regulatory Information Summaries, NUREGs, and Interim Staff Guidance documents (ISGs).

During the development of the package design and the application for a CoC, the applicant would also develop engineering drawings, fabrication specifications, calculation packages, and a safety analysis report. Among other supporting documents, the applicant would also prepare reports of tests and analyses that demonstrate that the package would comply with the Normal Conditions for Transport and the Hypothetical Accident Conditions in Part 71.²

The applicant for a Type B package CoC would submit an application, including a package evaluation that demonstrates, among other things, compliance with 10 CFR 71, Subparts E and F. The applicant would also submit a Quality Assurance (QA) Plan, which would be submitted in accordance with 10 CFR 71.37 (a) and which would seek NRC approval of the QA Plan under the provisions of 10 CFR 71, Subpart H.

Publicly Available Package Design Information – The extent of package design information that is placed in a Part 71 docket can be substantial. This information is publicly available unless the NRC agrees with an applicant's request to withhold certain information as proprietary.³ In spite of the extent and nature of docketed information, *EnergySolutions* maintains that this set of docketed, publicly available, package design information cannot always be sufficient to ensure that a entity could fabricate a package that would meet the requirements of either 10 CFR 71 or the approved CoC.

Loss of Package Design and Fabrication Control – There are several reasons why a fabricator that is not connected with the certificate holder cannot provide reasonable assurance of package design and fabrication. Principally, an independent fabricator would not have all the fabrication details that had been specified by the certificate holder. Perhaps more importantly, such a fabricator would not be aware of any changes in fabrication and materials requirements that were being developed by the designer of record, the certificate holder. Also, the fabricator would be unable to obtain prior approval of a fabrication change and could not determine which changes might require an amendment to the NRC-approved CoC.

¹ 10 CFR 71, Subpart D, Application for Package Approval and Subpart E, Package Approval Standards

² 10 CFR 71.71, Normal Conditions of Transport and 10 CFR 71.73, Hypothetical Accident Conditions

³ An NRC determination that requested information is indeed proprietary may not stand, if such information is later determined to be releasable under the Freedom of Information Act. See 10 CFR 9.28.

In these circumstances, design control interactions would be disconnected between the certificate holder and the fabricator. The certificate holder would most likely not even be aware of the fabrication. This type of fabricator would not have an established link with the certificate holder. The certificate holder (designer of record) would not be able to control any design or procurement changes that the fabricator made. The package quality, design and regulatory pedigree would slide into a state of indeterminacy. Demonstrating after the fact that such a package met the requirements for use, while possible, would be burdensome and complicated. To do so would require the involvement of and certification by the certificate holder.

Procurement control similarly would lapse. The situation with sub-tiered suppliers would be even more disconnected and uncontrolled. Vendors of nuclear grade items such as Type B packages typically have a formal, controlled process for communicating with their fabricators, suppliers, and Registered Users⁴, who are the licensees that ship and receive their packages. If a certificate holder does not know all the fabricators and suppliers, this important communication link is severed.

Licensee Inability to Comply with 10 CFR 71 – If a licensee were to load, ship, or use a package that had been fabricated without the involvement of the certificate holder, that licensee would not be able to demonstrate that such a package met its certification, quality, and safety bases. Several sections in 10 CFR 71 impose requirements on licensees, that is, shippers and receivers, which ensure that a package truly meets its design and safety basis. For instance, section 10 CFR 71.85 (c) states in pertinent part, “...*the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Commission.*” With no link between the certificate holder and fabricator, there is no practical way that a licensee can determine whether or not such a package is acceptable for use. A licensee that loads, ships, or receives such a package would not be able to demonstrate compliance with 10 CFR 71.

10 CFR 21 – Fabricating a package without the involvement of the certificate holder creates a variety of potential problems with meeting 10 CFR 21 requirements. Licensees, fabricators, sub-tiered vendors and suppliers, and the certificate holder would not be able to review fabrication and procurement issues for consideration under 10 CFR 21. As with uncertain design, quality, and certification bases, independent fabrication creates another level of indeterminacy in this case with respect to the requirements of 10 CFR 21.

⁴ See 10 CFR 71.17 (c) (3).