TROXLER

August 30, 2002

Mr. Martin J. Virgilio, Director
Mail Stop 8 A23
Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Request for exemption from an NRC interpretation of 10 C.F.R. 30.15(a)(9)(ii)

Dear Mr. Virgilio:

This exemption request is being sent to you in accordance with the requirements of 10 CFR 30.6. A copy has also been sent to Dr. Donald A. Cool along with a license application for exempt distribution of Troxler's CoreReader instrument.

Pursuant to 10 C.F.R. 30.11, specific exemptions, Troxler Electronic Laboratories, Inc. ("Troxler"), hereby applies for an exemption from 10 C.F.R. 30.15(a)(9)(ii) to the extent that the provision has been interpreted to be limited to "ionizing radiation measuring instruments" which have the sole purpose of measuring radiation in the environment. The requested exemption would enable the Nuclear Regulatory Commission ("NRC" or "Commission") to apply 10 C.F.R. 30.15(a)(9)(ii) to license Troxler's radiation measuring instrument known as the CoreReader for exempt distribution. As demonstrated below, the NRC's criteria for granting an exemption are satisfied.[1] In particular, the grant of an exemption should result in a substantial benefit to the public.

In determining whether to grant an exemption, the NRC also will consider the environmental impacts of the proposed action, 10 C.F.R. 51.30(a), and whether it can make a finding of no significant impact, 10 C.F.R. 51.32(a). A separate review of the environmental impacts related to this proposed exemption shows that it will not have any impact on the quality of the human environment.

Troxler requests that the exemption be issued by October 1, 2002. Troxler has invested substantial resources in developing the CoreReader and has been interacting with the NRC about it since February 2002. As a result, the NRC already is familiar with the device and its safety features. Under these conditions, further delay in distributing the device would result in an

[1] The NRC has provided additional guidance on criteria for exemptions involving exempt distribution licenses. See, Section 13 of NUREG-1556, Vol. 8, Program Specific Guidance About Exempt Distribution Licenses (1998). This guidance also is satisfied.

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unnecessary economic burden and delay the public's realization of the benefits that will result from using the device.

Description of the Device for which an Exemption is Sought

The CoreReader is an ionizing radiation measuring device that uses revolutionary technology to significantly improve the measurement of the specific gravity of asphalt in roads. As described in a separate risk assessment, eight exempt cesium-137 sources are arranged in a particular configuration
to provide the radiation necessary for probing the volume of an asphalt sample. A detector and software determine the specific gravity of the sample. Troxler has applied for a patent on the CoreReader.

Because the CoreReader significantly improves the determination of the specific gravity of the asphalt in roads, use of the CoreReader will substantially improve the quality and longevity of asphalt road surfaces. As a result, the public will benefit from reduce highway accident rates, reduced public expenditures on road repairs and replacements, and reduced environmental impacts associated with road repairs and replacements.

Regulatory Requirements

Troxler believes that the CoreReader can be licensed for exempt distribution in accordance with 10 C.F.R. 30.15(a)(9)(ii). Because the CoreReader is an ionizing radiation measuring device that contains eight exempt cesium-137 sources which are used for internal standardization and calibration as well as for measuring sample specific gravity, it meets the NRC's conditions for exempt licensing. Nevertheless, although the regulation does not specify the purposes for which such a device may be used, the NRC staff has interpreted this provision to apply only to ionizing radiation measuring devices which have the limited purpose of measuring radiation in the environment.[2] This interpretation would require the CoreReader to be distributed under a general license in non-Agreement States, even though the density-measuring purpose of the CoreReader would not substantially increase the risk associated with the instrument if it were used only to measure radiation.

NRC licensing of the CoreReader under a general license could lead to inconsistent licensing requirements in the Agreement States. Some Agreement States would require a specific license and some would impose different conditions on either a general or specific license. Such licensing requirements are not only inconsistent with the very low risk associated with the CoreReader but also present a substantial barrier to the commercial distribution of the CoreReader and, thus, to the public benefits that would result from its use in road building.

[2] It should be noted that because the NRC staff's interpretation is not included in the explicit language of 10 C.F.R. 3015(a)(9)(ii), an exemption by the Commission may not be needed. Rather, a deviation issued by the Director, Nuclear Materials Safety and Safeguards may suffice to enable the CoreReader to be licensed for exempt distribution.

Exemption Requested

The need for an exemption arises from the unnecessary regulatory burden that would inhibit adoption of this device if it were required to be distributed under a general license. There is no question that the CoreReader is a radiation measuring instrument that meets the safety standards in 10 C.F.R. 30.15(a)(9)(ii). However, because the CoreReader measures changes in radiation flux for the purpose of determining density, instead of measuring external environmental radiation, the NRC's interpretation of 10 C.F.R. 30.15(a)(9)(ii) would require the CoreReader to be licensed under the regulations that apply to gauges which contain far greater quantities of radioactive materials than incorporated in the CoreReader. These regulatory provisions would not increase safety but would decrease use of the device, thereby depriving the public of its benefits. For these reasons, Troxler requests an exemption from the NRC's interpretation of 10 C.F.R. 30.15(a)(9)(ii) to permit the CoreReader to be distributed under an exempt license.

Exemption Criteria

The Commission may grant an exemption from a provision in 10 C.F.R. Part 30 if that exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest per 10 C.F.R. 30.11(a). As shown in greater detail below these criteria are met. The exemption is authorized by law because no other legal requirement prevents the NRC from granting an exemption from this interpretation of a provision in its regulations. The exemption will not endanger life or property or the common defense and security because the device contains less than the legally allowed number of exempt sources which the NRC has already determined may be included in a device licensed under 10 C.F.R. 30.15(a)(9)(ii). Finally, the exemption is in the public interest because it will maintain safety while removing an unnecessary barrier to enhancement in the ability to build better, longer-lasting roads for public use.

The NRC has provided additional guidance on criteria for exemptions involving exempt distribution licenses. NUREG-1556, Vol. 8, Program Specific Guidance About Exempt Distribution Licenses (1998) ("NUREG-1556"). Section 13 of NUREG-1556 provides that an exemption should not be intended for a large class of licensees, should be limited to a unique situation, should be needed, may be supported by compensatory safety measures, and should be supported by a showing that alternative methods of regulation are not feasible. This guidance is satisfied by this request as discussed below.

Authorized by Law

The exemption is authorized by law because it would modify an interpretation of a provision in 10 C.F.R. 30.15(a)(9)(ii). This provision was promulgated by the NRC under its authority in the Atomic Energy Act of 1954, as amended, and is not subject to any other statutory or regulatory requirements. Accordingly, the NRC has the authority to grant this exemption from its own interpretation of its own requirements as long as the NRC meets the other requirements for granting an exemption. The other exemption requirements are met for the reasons discussed below.

Will Not Endanger Life or Property

The requested exemption will not endanger life or property because no significant radiological impacts would result. The NRC has repeatedly determined that the distribution of exempt quantities of radioactive materials poses a negligible risk to the public health and safety. Just such a safety determination supported the NRC's adoption of 10 C.F.R. 30.15(a)(9)(ii) which authorizes the exempt distribution of ionizing radiation measuring instruments containing up to ten exempt sources. That safety determination bounds the safety implications of this exemption request for the CoreReader because: (1) this request would authorize the distribution of an ionizing radiation measuring instrument containing only eight exempt sources; and (2) the purposes for which the CoreReader would be used create no greater risk to public health and safety than the purposes for which other ionizing radiation measuring instruments are used. Radiation doses received as a result of transporting, using, and disposing of the CoreReader would be minimal, the amount of radioactive material involved is very low, the radioactive material is firmly enclosed in the CoreReader, the design of the CoreReader will limit any accidents that could result in the release of radioactive materials, and Troxler will accept and encourage return of the devices for licensed disposal of the cesium sources.

The minimal risk to public health and safety resulting from the exempt distribution of radiation measuring devices containing cesium-137 has been affirmed in NUREG-1717. It reports that under both normal and accident conditions, the exempt distribution of devices containing up to ten exempt cesium-137 sources would not result in overexposures to either the public or to workers. Disposal of such devices also has been shown not to result in significant exposures. Nevertheless, Troxler has committed to encouraging each user of the CoreReader to return it to Troxler for disposal at the end of its useful life. Troxler will dispose of the exempt sources as licensed material.

Distribution of the CoreReader under a general license instead of as exempt would not reduce its minimum impact on public health and safety. Under either licensing regime, as modified by Troxler's commitment to take back the CoreReader at the end of its life for disposal and to track any transfers of the devices, the CoreReader would be constructed, transported, used and disposed of in the same way.

Will Not Endanger the Common Defense and Security

Distribution of these devices will not endanger the common defense and security because several factors make the CoreReader an unattractive target for the diversion of radioactive materials. Among these factors are the very low activity in the exempt sources, the physical nature of the exempt sources, the inaccessibility of the exempt sources in the construction of the CoreReader, the size and weight of the CoreReader and the limited access to a CoreReader under its expected conditions of use. All of these factors reinforce the conclusion that there is a very low risk of theft of a CoreReader for the diversion of its contained exempt sources.

Distribution of the CoreReader under a general license instead of as exempt would not reduce the already very low risk of theft of a CoreReader and, thus, would not reduce the risk to the common defense and security.

Otherwise in the Public Interest

The exemption is clearly in the public's interest. Troxler's extensive experience with road building shows that the devices currently used to measure the specific gravity of asphalt are far less accurate than the CoreReader, result in measurements that are significantly less reproducible and are subject to human error. These limitations on current specific gravity measuring devices are overcome by the CoreReader through its unique design By subjecting an asphalt sample to a pattern of radiation from distributed sources and by analyzing the transmitted radiation, a sample's specific gravity can be measured accurately. The results are higher quality, longer-lived roads that have a lower repair rate.

Several benefits result from this improvement in road quality. Reduced road degradation rates reduce accidents and environmental impacts from potholes and other degraded road conditions. Reduced road degradation rates also reduce the costs and environmental impacts related to road repair and replacement.

These benefits would not be as widely realized if the CoreReader were distributed under a general license. Road constructors have told Troxler that they would rather continue to use instruments that are known to be less accurate than deal with the regulatory requirements that accompany a general license. If the CoreReader were licensed to be distributed as exempt, it is far more likely that it would be adopted by a significant fraction of the road building community. Moreover, as discussed above, distribution of the CoreReader as exempt would not result in significantly greater impacts than would its distribution under a general license. Thus, distribution of the CoreReader as exempt could result in substantial benefits to the public with no little additional or significant adverse consequences.

NUREG-1556 Guidance

For the following reasons, each of the elements of the guidance in NUREG-1556 is met by this exemption request.

- The exemption is not intended for a large class of licensees. It would apply only to the CoreReader which is a unique product. If Troxler receives the a patent on the CoreReader, this will further limit the class of licensees who could attempt to seek a comparable exemption for themselves.

- The exemption request is limited to a unique situation because the device uses an array of exempt sources that have been arranged in a specific manner to measure density and a patent for that use has been applied for.

- The exemption is needed for the reasons related to the public interest discussed in detail above.

- Compensatory safety measures are not necessary because the NRC has determined that ionizing radiation measuring instruments containing ten exempt cesium-137 sources are safe to distribute as exempt and there is nothing about the density measuring purpose of the CoreReader that increases the risk from its distribution, use or disposal. Nevertheless, as discussed above, Troxler has committed to tracking transfers of CoreReaders and to taking back CoreReaders and disposing of their sources as licensed material.

- Alternative licensing is not feasible for several reasons. General or specific licenses would impose regulatory burdens that are considered unnecessary by potential users and, therefore, are unacceptable to them. The lack of reciprocity for general licenses will result in unnecessary and costly administrative burdens due to the need to comply with differing requirements for licensing, fees, and registration in the 32 Agreement States. Furthermore, some Agreement States may require a specific license in some cases, thereby further increasing the unnecessary regulatory burden and cost.

Conclusion

For the reasons discussed above, the NRC should grant an exemption from its interpretation of 10 C.F.R. 30.15(a)(9)(ii) so that the CoreReader can be distributed as exempt consistent with its minimal risks and so that the public can realize the benefits of its use in the construction of longer-lasting, higher-quality roads.

Sincerely,

William F. Troxler, Jr.
President

Cc: Dr. Donald A. Cool, NRC