



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

April 24, 2002

MEMORANDUM TO: John W. Hickey, Chief
Materials Safety and Inspection Branch/IMNS

FROM: John Jankovich *John P. Jankovich*
Materials Safety and Inspection Branch/IMNS

SUBJECT: SUMMARY OF MEETING WITH TROXLER,
APRIL 22, 2002

Representatives of Troxler Electronic Laboratories, Inc., Research Triangle Park, North Carolina, presented a briefing to IMNS management on April 22, 2002, to describe the design of their density gauge and to discuss the possible authorization of the gauge as an exempt product. The briefing was a follow-up to a previous meeting on February 6, 2002, where Troxler presented these issues to the NRC staff. Messrs. William F. Troxler, President and Chairman, and Stephen Browne, Radiation Safety Officer, gave the presentation.

The presentation addressed the following issues:

- the device, called a CoreReader, is designed to measure the density of asphalt samples for road construction;
- the primary use of the device will be in laboratory settings, in fixed-based or mobile (trailer-type) laboratories;
- the source assembly consists of eight exempt quantity sealed sources of 10 μ Ci, Cs-137 each;
- external radiation levels are low;
- in Troxler's view, the device is a radiation measuring instrument as described in 10 CFR 30.15(a)(9); however, Troxler understands the staff's position that the CoreReader is not a radiation measuring instrument;
- distribution, use, and disposal of the device would be more limited than those of other exempt products;
- risks associated with use, diversion, and disposal are comparable to other exempt products;
- Troxler intends to send a written inquiry to NRC to determine whether the product could be authorized as an exempt product with an exemption from the provisions of 10 CFR 30.15 (a)(9);
- Troxler believes that granting an exemption would be consistent with the regulatory principles of maintaining safety and reducing unnecessary regulatory burden.

The NRC participants outlined to the Troxler representatives that

- the staff will consider a written request from Troxler on this matter;

- Troxler should consider including specific proposals for resolution in the written submittal.

A set of the presentation slides is attached.

Participants:

1. Troxler Electronic Laboratories, Inc.
William F. Troxler, President & Chairman
Stephen Browne, RSO
Sheldon L. Trubatch, Legal Counsel
Michael Bienvenu, Technical Specialist
2. Nuclear Regulatory Commission

Donald A. Cool, Director, IMNS
John W. Hickey, Chief, MSIB/IMNS
J. Bruce Carrico
John P. Jankovich
Anthony S. Kirkwood
William R. Ward
3. Others

Frieda Taylor/State of California

Enclosure: As stated

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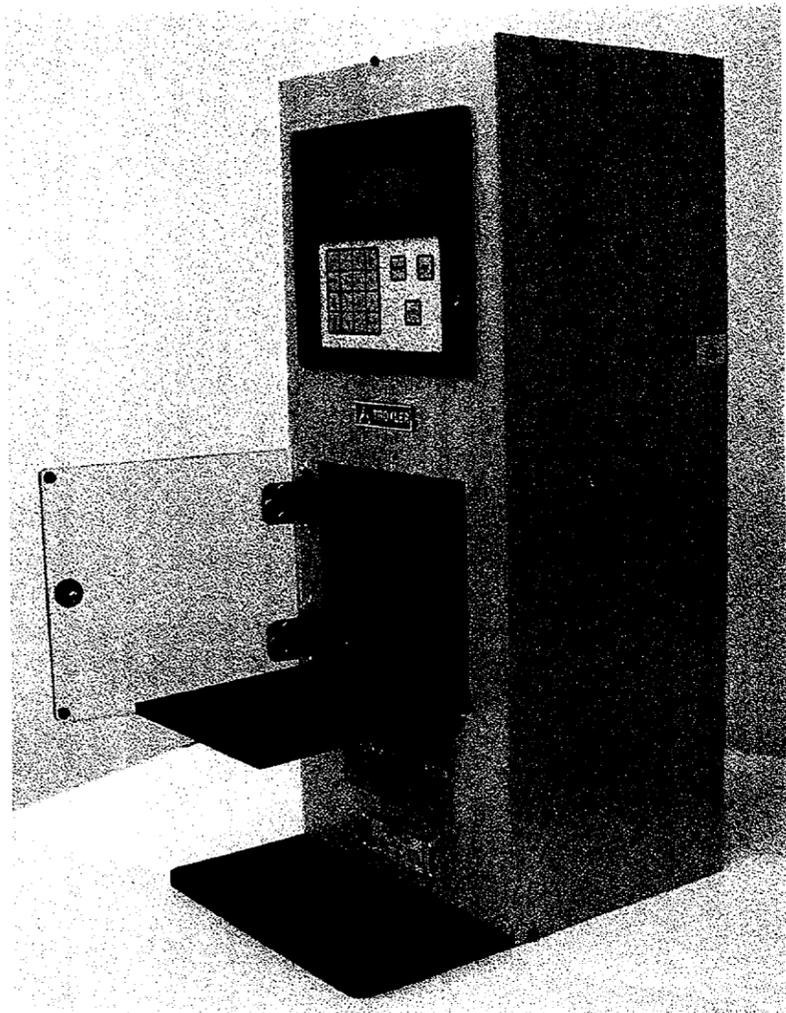
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CoreReader

The CoreReader is a bench-top ionizing radiation measurement instrument employing proprietary software to interpret the gamma-ray transmission spectrum from an array of exempt-quantity sources to estimate the specific gravity of a compacted asphalt sample



4/19/02

Troxler's Licensing Request

- Issue a license to Troxler under 32.14 to manufacture and distribute the CoreReader as an exempt device under 30.15(a)(9)

Device Design and Construction

- Dimensions: 12.2" w x 10.2" d x 29" h
- Weight: 77 lbs.
- All metal construction
- Lead shielding
- Sources inaccessible and secured against unauthorized removal
- Design, construction, labeling, quality assurance, radiation levels and prototype testing presented in detail to NRC staff at previous meeting
- No safety-related concerns expressed by NRC staff

Source Details

- Cs-137, exempt quantity sealed sources, 10 microcuries each
- Sealed in Plexiglass disk, 1" diameter x 0.175" thick
- 8 sources (80 microcuries total)
- Multi-source geometry essential to operation of device

Device Radiation Levels

Distance or Location	Max. Dose Rate (mrem per hour above bkgd)
In sample chamber	1.1
5 cm	0.2
30 cm	0.05
100 cm	Not detectable

- Measured with Bicron Micro Rem survey meter with organic scintillator calibrated to Cs-137

Radiation Risks

- Routine operation (extreme case)
 - Whole body dose would not exceed 100 mrem per year (based on 2000 hours per year at 30 cm)
 - Extremity dose would not exceed 10% of annual limit (based on hands being inside sample chamber for 2000 hours per year)
- Accident (worst case)
 - Inhalation or ingestion of total activity in device (not credible) would not exceed annual limit on intake for Cs-137

Applicability of 30.15(a)(9)

30.15 (a)(9)	CoreReader
“Ionizing radiation measuring instruments...”	<ul style="list-style-type: none"> • NaI detector, gamma ray spectrometer. • Nothing in rule or statement of consideration limits purpose of instrument.
“containing, for purposes of internal calibration or standardization, one or more sources of byproduct material...”	<ul style="list-style-type: none"> • Sources used for internal calibration and standardization. • Other purposes not specifically precluded in rule. • Purpose doesn't affect safety.
“provided that each source contains no more than one exempt quantity set forth in 30.71, Schedule B, and...”	<ul style="list-style-type: none"> • Each source contains no more than the exempt quantity for Cs-137 (10 microcuries)
“each instrument contains no more than 10 exempt quantities.”	<ul style="list-style-type: none"> • Contains 8 exempt quantities

NRC Concerns

(as we understand them)

- 30.15(a)(9) not applicable because inferred intent limits purpose to measuring environmental radiation
- Granting an exemption for CoreReader would set a broadly applicable precedent
- Material control
- Bundling exempt sources

Safety Not a Concern

- No indication from previous meeting or conversations with NRC that safety of CoreReader is a concern (the question has been asked)
- GL 99-01 concluded multiple exempt sources in a device not a safety concern
- Lack of safety concern corroborated more recently by NRC research
 - Systematic Radiological Assessment of Exemptions for Sources and Byproduct Materials, NUREG-1717
 - Risk Analysis and Evaluation of Regulatory Options for Nuclear byproduct Material Systems, NUREG/CR-6642

Material Control

- Theft and diversion
- Disposal
- Accountability

Material Control

- Theft and diversion
 - Most thefts involve portable nuclear gauges stolen from open vehicles (e.g., pickup trucks)
 - Theft unlikely because:
 - CoreReader bulky and heavy
 - Used indoors in fixed locations, out of public view, and under better security
 - relatively few units expected to be in use
 - Diversion unattractive because of low activity (e.g., a moisture-density gauge contains 100,000 times more exempt quantity units)
 - low activity + low dose rate = low risk to public

Material Control

- Disposal of device
 - Rule authorizes disposal in ordinary waste
 - Low activity presents negligible public exposure risk in event of disposal
 - Troxler has an industry-leading source recovery and disposal program to prevent orphan sources
 - Troxler will encourage and accept return of devices for disposal as licensed material via device labeling, literature, and website

Material Control

- Accountability
 - Troxler will maintain permanent records of all device transfers including:
 - Name and address of transferee
 - Model and serial of device
 - Date of transfer

Bundling Exempt Sources

- Generic Letter 99-01 addressed concerns over bundling more than 10 exempt sources in devices
- Bundling of 10 or fewer exempt sources affirmed as not presenting new safety issues
- Devices with no more than 10 exempt sources not found to violate NRC requirements
- NRC determined distribution of sources for bundling in devices not allowed
- Exemption in 30.15(a)(9) unaffected

Bundling Exempt Sources

- CoreReader does not represent bundling because multiple exempt quantities are not used in lieu of a single larger source
- Possibility of exempt distribution not identified until after device designed
- Multi-source geometry essential to achieving accuracy goal by averaging over larger sample volume to reduce error from sample inhomogeneities

Proposed Path Forward

- Exemption from 30.15(a)(9)
 - Section 30.11 authorizes the Commission to grant exemptions from requirements of Parts 30 through 36 and 39
 - Exemption requested from NRC interpretation that creates limiting purpose on ionizing radiation measuring instruments covered by 30.15(a)(9)
 - Exemption based on geometric necessity implements Commission performance goals while suitably limiting scope of applicability

Proposed Path Forward

- Broadly applicable precedent not a concern because...
 - Exemptions are discretionary (NRC has refused to grant “copycat” exemptions)
 - Possibility of many similar requests speculative and, therefore, premature
 - Possibility of setting a precedent not a factor legally recognized in 30.11 in granting exemptions, otherwise all but most unusual, singular requests for relief would be denied, contrary to NRC practice.
 - If other requests materialize, NRC can deal with them at that time or initiate rulemaking

Basis for Granting Exemption

- Will not endanger life or property or the common defense and security
 - NRC has repeatedly determined that exempt quantities pose a negligible risk to health or safety
 - Normal or accident conditions will not cause overexposures to workers or members of public
 - Troxler will maintain records of transfers
 - Troxler will take devices back when no longer needed
 - Laboratory instrument has low risk of theft
 - Low activity unattractive for diversion

Basis for Granting Exemption

- Is otherwise in the public interest
 - CoreReader is designed for quality control measurements of highway construction materials
 - Alternate measurement methods are less accurate and reproducible and more subject to human error
 - The ultimate benefits are higher quality pavements, reduced road maintenance (lower overall cost), and increased safety
 - Actual benefits outweigh minimal theoretical risk

Basis for Granting Exemption

- Exemption is not intended for a large class of licenses; limited to a unique situation
 - An exemption would not affect a whole class of licenses, but would only apply to the CoreReader (a unique product)
 - Would not likely lead to a large number of similar exemption requests, because similar products do not exist (patent applied for)
 - An exemption can be narrowly tailored to the use of multiple sources for geometry reasons (similar to multiple sources for energy reasons)

Basis for Granting Exemption

- Why it is needed
 - To avoid unnecessary and burdensome regulatory requirements which increase costs and may discourage use of the CoreReader
 - The NRC has already determined that the amount of source material in the CoreReader represents a negligible risk and may be safely distributed as exempt either in the form of individual sources or incorporated in devices

Basis for Granting Exemption

- Proposed compensatory safety measures
 - None are necessary as the NRC has repeatedly determined that the amount of source material in the CoreReader represents a negligible risk and may be safely distributed as exempt either in the form of individual sources or incorporated in devices

Basis for Granting Exemption

- Alternative methods and why not feasible
 - CoreReader complies with all safety-related requirements of 30.15(a)(9)
 - Specific or general licensing are inappropriate and unnecessarily burdensome for the form and quantity of source material, purpose of use, and limited risk
 - No reciprocity for general licenses
 - Varying requirements for licensing, fees, registration, etc. in 32 Agreement States creates unnecessary and costly administrative burden
 - Requirement to provide extensive information prior to purchase decision adds a burden

Basis for Granting Exemption

- Alternative methods and why not feasible (cont.)
 - Agreement States may require a GL device to be put on a specific license if the user has one, which adds a complicating second set of labeling, license verification, and reporting requirements for Troxler
 - General licensee must appoint responsible person who has many responsibilities that are administratively burdensome and require knowledge and tracking of many different events that trigger actions to be taken

Basis for Granting Exemption

- Alternative methods and why not feasible (cont.)
 - General license will not make the device inherently safer and will not significantly reduce the already minimal risk
 - Alternatives would discourage broad adoption of device by road builders, thereby depriving public of safer, longer-lasting roads

NRC Performance Goals

Goals	How Met
Maintain safety, protection of the environment, and the common defense and security	NRC has already found this quantity of source material is safe for exempt distribution
Increase public confidence	No relaxation of any safety rules. No compensatory safety measures necessary.
Make the NRC activities more effective, efficient, and realistic	Consistent with Materials Risks Study. Risks no greater than for distribution of multiple individual exempt quantities.
Reduce unnecessary regulatory burden on stakeholders and associated costs	The burden of general licensing would go beyond what is necessary and sufficient to provide reasonable assurance that public health and safety, the environment, and the common defense and security will be protected and would increase costs