

Mr. Carl Baldwin, RSO
 Scan Technologies Inc,
 303 Jacobson Drive
 Rock Branch Industrial Park
 Poca, WV 25159

SUBJECT: DISCONTINUE REVIEW OF SCAN TECHNOLOGY APPLICATION FOR
 REGISTRATION OF MODEL CM-100, CONDUCTIVE MATERIALS MOISTURE
 MONITOR

Dear Mr. Baldwin:

This letter is in response to your application dated August 9, 2001, requesting the evaluation and registration of the Model CM-100 Conductive Materials Moisture Monitoring device. In reviewing the application, we find the application is lacking significant amounts of information for us to reach a decision. We need additional information to conduct a safety evaluation of your application. Therefore, we request that you address the issues outlined in the Enclosure.

With incomplete documents and unavailability of adequate information the NRC Staff is unable to complete a safety evaluation of your device. Therefore, we have discontinued the review of your application. This is without prejudice to providing the requested information. You may choose to answer the questions in the Enclosure or to resubmit the entire application with the additional information we requested.

If you have any questions, please contact me at (301) 415-7894 or John Jankovich at (301) 415-7904.

Sincerely,

/RAI

Ujagar S. Bhachu, PEng., CEng., F.I. Mech. E
 Materials Safety and Inspection Branch
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

Enclosure:
 cc. W/Enclosure: Shirley Crutchfield, LFARB

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IMNS r/f SSD Case 01-37

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REQUEST FOR ADDITIONAL INFORMATION

On January 4, 2001, Scan Technologies Inc. requested the Nuclear Regulatory Commission for the safety evaluation and registration of a device CM 100 Conductive Materials Moisture Monitor. Following a preliminary NRC review the application was withdrawn on July 2, 2001. Scan Technologies resubmitted the application on August 9, 2001. We need additional information to complete a safety evaluation of the device. Scan Technologies Inc. is requested to submit the additional information regarding the following issues:

1. MISSING AND ILLEGIBLE DOCUMENTS

- 1.1 Sections 6 and 7 of your application are missing. Please provide copies of these sections.
- 1.2 Please provide a legible copy of the sections entitled "Prototype Testing" with decipherable photographs.

2. OTHER COMPANIES INVOLVED

- 2.1 Your application states: "The Kanawha Scales & Systems, Inc. shares facilities with Scan Technologies, Inc. Devices will be distributed by Scan Technologies, Inc. Final source installation, device label attachment and installation may be performed by either jointly or independently. No manufacturing will be performed by the either party beyond source installation and label attachment."

Please note that it is a regulatory requirement that installation, removal and replacement of the source, radiation profiles be measured by calibrated instruments and recorded and all installation performed by an individual specifically licensed by the Nuclear Regulatory Commission or an Agreement State. It is equally important that all records are available and maintained at a single location. Please provide details of the arrangements and the working relationship between Kanawha Scales & Systems, Inc. and Scan Technologies Inc.

3. DESIGN

- 3.1 Please describe how the Shutter Positioning Disc (mechanical on/off indicator) is attached to the sealed source shutter control shaft.
- 3.2 It is our understanding that the installed weight of the unit, including gauge, detector, C-frame, and support frame, is approximately 750 kg. Please confirm this, or provide the correct information. Please provide the total weight breakdown by component.

- 3.3 Demonstrate that, when the source indicator position disc is padlocked in the closed position, the force exerted by the shutter drive will not break either the connection between the shaft and the drive, or the connection between the shaft and source indicator position disc.
- 3.4 Indicate whether it is possible to manually rotate the source position indicator disc to the closed position against the force of the motor when the motor is operating and the shutter is in the open position. If so, indicate the force or torque required to do so.

4. DRAWINGS

- 4.1 The drawings attached to the application do not provide sufficient information. As a result we are unable to complete our review and evaluation of your application. Resubmit your drawings and make sure that as a minimum these drawings contain specifications of materials, dimensions, tolerances, assembly methods, and other information critical to design of the device that is not described elsewhere in your application. Drawings that show part numbers must be accompanied by a part list.

In particular, we need to have sufficient information in order to assess the integrity of the source housing containment, safety features, functionality and the working of all moving components. Therefore, please submit complete engineering drawings, which specify the materials and tolerances for all such components.

- 4.2 Drawing No. 7810-90-0028, Rev. 1: Please provide the sealed source shutter spring rating, mechanical and thermal properties and material specifications. Provide normal air quality specifications for the air solenoid. This drawing shows that the pin holding the shutter position indicator disc to the shaft penetrates both sides of the disc hexagon nut. Drawing No. 7255-00-0006, Rev. 3, shows that the pin penetrates only one side of the disc hexagon. Please clarify this apparent discrepancy.

Also, please provide materials and dimensions of the shaft (item 32), details of the connection between the actuator (item 22) and the shaft (item 32), detailed engineering drawings of items 21 and 34 and include connection to the actuator, and to item 34.

- 4.3 Drawing No. 7255-00-0006, Rev. 3, shows the hexagon attached to the plate by a fillet weld, however it does not show how the outer ring is attached to the plate. Indicate how the outer ring is attached to the plate. The drawing indicates a zinc plate and chrome-passivated finish. Please provide the details of the process and, how it is applied, and whether it is applied before or after the zinc plating. Indicate where each finish is applied on the component.

- 4.4 Drawing 8025-90-0026, Rev. 0 indicates the wall thickness of the outer shell (item 12) and the external dimensions of the device. Provide the internal dimensions, including tolerance, of the two areas that contain the rotary shutter assembly (Drawing No. 6625-90-0001) and the source holder and tube extension assembly (Drawing No. # 6205-90-0006). This drawing does not show the cross-section detail on the left side of the device, where the rotary shutter assembly (Drawing No. # 6625-90-0001) is mounted. Provide an engineering drawing that includes the detail of this area. The drawing provides a front view and a side cross-section view only. Please include a top view.

Provide engineering drawings that illustrate how the flat face of item 8 of the rotary shutter assembly (Drawing No. 6625-90-0001, Rev. 0) fits to the curve of the cylindrical surface of the outer shell. Provide the same for item 4 of the source holder & tube extension assembly (Drawing No. 6205-90-0006). Explain the thin vertical rectangular component shown along the centerline that passes through the shutter collimator opening and the source.

- 4.5 Drawing No. 6625-90-0001, Rev. 0: Provide dimensions for the drawing. You do not need to provide dimensions for the rotary shutter since they were provided on Drawing No. 6625-00-0005, Rev. 1. Please ensure that you include the following:
- the inside diameter of the open tube in which the shaft rotates. As seen on the drawing, it appears that the opening of the left end is narrower due to the metal sheeting enclosing the left end flange bearing. Please provide the diameter at this point also;
 - the external dimensions of the assembly;
 - the minimum clearance between the rotary shutter and the shielding housing.
- 4.6 Drawing 6205-90-0006, Rev. 2: Provide dimensions for the drawing. Explain the "cutout" or hole in the tube front plate (item 4) that appears to be located beneath the pull-out handle base on the end of the assembly. We note that Drawing No. 8025-90-0026, Rev. 0, does not show this hole in the plate. Explain the function of the "Circlip Spacer" (item 6). Indicate the materials for all components. You do not need to provide the shielding material since it was discussed in the text of the application.

5. MATERIALS

5.1 It is our understanding that all materials listed as "Z/P" are zinc-plated mild steel, and as "CAD PL" are cadmium-plated mild steel. Please verify this, or provide corrected information. Indicate the materials for all components not specified as "Z/P" or "CAD PL." You do not need to provide the material for the rotary shutter since it was provided on Drawing No. 6625-00-0005, Rev. 1. You do not have to provide the shielding material since it was discussed in the text of the application.

5.2 Shielding material is indicated the cast neutron shielding (part# 5805-00-0197 as two types; 1) boric acid doped plaster of Paris in which a maximum concentration of high-density polyethylene beads is suspended; 2) high-density polyethylene beads with a polyester binder, doped with boric acid.

Please indicate how homogeneity and uniform spread of the beads is assured. Please provide the mechanical thermal and chemical properties of the shielding material. State the test methods, frequency and rejection and/or degradation criteria for the composite shielding material during the operating life of the gauge.

6. SEALED SOURCES TO BE USED IN CM-100

6.1 Section 1.5 of your application specifies the use of sealed source Model CVN-10 which is listed on registration certificate NR-0360-S-116-S. However, in the Appendix labeled "Source SS&D Registration," you have included the registration certificate NR-0136-271-S for the Model CVN.CYn Series and Frontier Technology Corporation registration certificate NR-298-S-102-S for FTC Series.

If you intend to use the Model CVN-10 source, please provide the ANSI N542 classification for this sealed source. If you wish to use model series CYC.CYn, please specify the exact model to be used in CM-100. The manufacturing, capsule materials of construction and configuration of the sealed sources covered by the above certificates vary considerably.

Please delineate which source model or models you intend to use and provide the details of the sealed source models used in the prototype tests of the device CM-100. Please confirm that sealed source housing has sufficient geometry to accommodate these sources safely.

6.2 Section 1.5 of the application states under the heading Activity "75 micrograms per capsule, 1-4 capsules per device. 100 microgram nominal activity per device, source models can be mixed, ...the manufacturer has set a maximum total activity of 100 micrograms, +/- 2.0% for new source installation. There is no

lower activity limit." These are contradictory statements. Is 100 microcuries nominal or maximum?

Your application listed a maximum of 75 micrograms per capsule. Please confirm that this is considered the maximum and includes the highest quantity permitted including any upper end loading tolerance.

Also confirm that the presence of dissimilar metals in the vicinity of the sealed source will not adversely impact the sealed source containment integrity during the source useful life.

- 6.3 Some of the sealed source models you listed in your application are too small to carry a label or a source serial number. Please address the accountability and traceability measures you will use related to such sources.
- 6.4 Please provide estimated frequency of source change. Please state the half working life of the source considering the ionization and the random neutronic instantaneous fission process.

7. ELECTRONICS CONTROL AND OPERATOR'S TERMINAL

- 7.1 You have stated in your application that normally the control cabinet may be mounted within 15 meters of the device C-frame. In the event the loss of the electrical power supply leads to the loss of air supply during normal operations or during maintenance, please indicate what provisions have been made in the design to alert the personnel that the shutter is stuck open and ensure that individual will not be in the radiation beam when attempting to check whether the source shutter is open or closed.
- 7.2 Section "Principle Operations" of your application stated "Fast neutrons and Gamma rays are produced by a californium-252 source contained in a shield source holder in upper arm of the monitor." While this statement is factual, please consider alerting the operator and the maintenance personnel regarding to the presence of alpha radiation generated by californium-252 and how its effect is mitigated by the device housing.

8. RADIATION DOSE ANALYSIS

- 8.1 We agree with your statement that operators of the CM-100 should never receive a dose of ionizing radiation higher than the maximum for the general members of the public. Your calculation conducted with conservative assumptions have yielded a dose of 686.4 mRem/year. Your assumptions of 40 hrs/week, 52 weeks/year are overly conservative. Please consider the use of more realistic assumptions which will clearly demonstrate that the calculated dose rate is under regulatory limits of 100 mRem/year.

9.. EXTERNAL RADIATION LEVELS

- 9.1 The highest reading in Table 1 for the 3° radiation beam collimator was at point E (on the top of the gauge). Table 3 for the 4° radiation beam collimator provided only readings for points A, C, and H. Please explain why readings were not given for points E, G, J, M, K, or B, which were higher readings than H for the 3° collimator.
- 9.2 Your application indicates that the radiation levels do not increase when the shutter is opened, except in the beam. Table 3 indicates that the reading for point H, which is at the edge of the beam face of the gauge, increased from 2.5 $\mu\text{Sv/hr}$ to 3.5 $\mu\text{Sv/hr}$ at 100 cm.. In light of this, please clearly state the maximum radiation levels for the shutter open position at 5, 30, 100 cm, for both 3° and 4° radiation collimators. Along with the radiation profiles to be provided to the users, please consider including the external radiation levels in the beam at 5, 30, and 100 cm.
- 9.3 Your application states that radiation surveys with 3° collimator were performed on May 17-18, 2000 with Ludlum Model 12-4 Neutrons Dosimeter, S/N 76633, calibrated on July, 1999. ANSI N538-1979, Section 7.3 requires that survey meters used to measure stray radiation shall have been calibrated to center of the probes active volume not more than six months prior to date of these tests. It appears that you conducted tests with survey meter that did not comply with ANSI requirements. Please address this discrepancy and confirm that calibration procedures were in compliance with ANSI N323.

10. PROTOTYPE TESTING

- 10.1 Your application states that ON/OFF mechanism was cycled 500 times without failure. Please provide the number of cycles per year expected in typical operation. Please provide the stiffness of the spring and the maximum temperature at which the spring may loose its capability to keep the shutter in the closed position.
- 10.2 You have indicated in your application that prototype testing was performed on CM-100 device as required by Australian law prior to the sale of the device in Australia. The tests carried out were in compliance with NHMRC " Code of Practice For The Safe Use of Radiation Gauges, October 1990." We are not familiar with this standard, please supply a copy of this standard.
- 10.3 In support of your application you have cited the performance history of eight devices installed in foreign countries. The performance data of these devices spans from less than one to 9 years. It appears that a "pass" of functional test would not record a shutter failure. Please provide information on malfunctions of shutters if any.

To be able to credit this performance history as a basis to lend support to your application we would also need information on leak tests to verify that external radiation levels remained unchanged during the device operations.

- 10.4 Section 3.1 of the Test Report in the Appendix states that dummy source capsules were used during each test which then were replaced by actual sources after the tests to enable dose rate measurements to be made. Section 3.2 states that "within normal measurement variations no increase in the radiation dose rate levels occurred" after the tests. Regarding the drop test, Section 4.4.2.a (under Header 4.2) states that some internal distortion occurred since the shutter could not be readily rotated after impact.

Please specify the measurement tolerances used. We have noted that the test procedures did not include a leak test. In order to confirm the post test containment integrity of the device, please confirm that an actual source was installed and radiation levels were measured and remained unchanged following the drop test or provide additional information demonstrating that there would not have been leakage of the source as a result of the drop test impact.

- 10.5 The "reasoned argument" provided in lieu of actual vibration testing does not provide adequate assurance and as such is not acceptable.

Please provide complete testing procedures and results for the vibration testing, including the pass/fail criteria. Also, we have noted that the test procedures described in the Test Report did not include a leak test. You must provide sufficient information to demonstrate that there would be no leakage of the source as a result of the testing.

- 10.6 Drawing 7810-90-0028, Rev. 0. is missing from the application. Please provide details and a drawing of Kinetrol actuator. Please ensure that the drawing addresses all issues identified for Drawing. 7810-90-0028, Rev. 1. Was a Kinetrol actuator installed in the 30 foot drop test unit or did you test this actuator separately?

- 10.7 For fire protection, a "reasoned argument" is provided in Appendix 4 of the Test Report. The text of the application seems to indicate that an actual test was conducted; however, the Test Report clearly states that an engineering evaluation of the fire protection materials was performed. Please provide the rationale how the test results for the materials are applicable to the device.

11 LABELING

- 11.1 In order to ensure that the labeling will be large enough to be easily readable, please specify the minimum dimensions for the label, letter height and radiation symbol size. Please specify the minimum thickness of the label. Figure 3, "Picture of Device Label" shows four holes in the corner which suggests to us that the label is to be riveted to the device. Please confirm this or provide methods of label attachment.
- 11.2 The device CM-100 to be licensed specifically. Therefore, showing the general distribution license number on the label may lead to confusion as to whether the device was intended for use under a general license. You may list only your possession license number for identification purposes. Please also consider including on the label the ANSI gauge classification.
- 11.3 The installation procedures in the instruction manual do not address the issue of placing the label on the device. Please note in the manual that the device label must be affixed where it will be readily visible. Please provide an updated copy of the procedure that include these instructions.

12. CONDITIONS OF USE AND STORAGE

- 12.1 Your application indicates that the device will be used in ambient temperatures (although protected from direct sun, ice, snow, and rain). Your application states an operating range of 0°C to 45°C, with a wider range from -5 to 45°C for storage. In the continental USA normal ambient temperatures in a facility without temperature control could exceed this lower limit. Based on the information you have provided, we consider restricting the operating temperature range for you device to -5°C to 50°C. If you wish to operate or store the device at lower temperature, please provide additional information to demonstrate functionality of the device for the desired temperature range.
- 12.2 The application indicates that the source enclosure is vented to allow the escape of gasses in the event of a fire. Please identify the amounts of the gasses emitted and confirm that escaped gases would not compromise the containment integrity of the device or precipitate degradation of the source closure materials.

13. MISCELLANEOUS

- 13.1 Your Instruction Manual is marked as copyrighted. Please provide a waiver because documents provided to the NRC are publically available and must be reproduced. We request that you refrain from submitting proprietary information in support of a registration of your device. If you found it necessary to submit drawings or documents that contain confidential information, please either provide a waiver regarding the proprietary nature of these drawings and documents, or if you wish to maintain the proprietary classification, you must execute a notarized affidavit as specified in 10 CFR 2.790.

You must list all portions that you wish to be withheld proprietary along with your reasoning as to why that is appropriate. For each document or portions of document please submit two copies. One copy should be an unmarked copy containing all information. The second copy should have removed from it all information that you wish to be held proprietary. The reproducible copy will be placed in the NRC's public document room.

- 13.2 On page 33 of the Instruction Manual you stated that the source loading procedure must only be performed by a licensed radiation person. This can lead to misunderstanding since "licensed radiation person" is not defined and not in use by the nuclear industry . A more definitive wording is found on page 32 of your manual which states that the procedure must be performed by persons "specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State". Please make appropriate changes throughout the Instruction Manual.
- 13.3 Page 66 of the Instruction Manual directs the user to "See Emergency Procedures on page 66". There are no emergency procedures on page 66, however we found emergency procedures on page 15. Please correct this apparent discrepancy.
- 13.4 Pages 15 and 66 of the Instruction Manual provide information to users regarding emergency and normal shut down of the device. In order to ensure that the users do not approach the device in the case of a return spring failure, the manual should direct users to verify that the shutter has returned to the closed position by verifying that the mechanical shutter position indicator is in the OFF position. Please provide the needed additional guidance or provide additional information addressing this issue.
- 13.5 Page 86 of the Instruction Manual provides procedures for off-belt calibration of the device. Step 4 directs users to place the container, containing the sample to be measured, in the radiation beam in the off-belt position. The note below Step 4 states that the user may need to remove the device standard enclosure to allow the container to be placed in position. Step 5 directs the user to set the

sample container to the same height as the normal on the belt position, requiring the measurement to be taken between the bottom of the device and the top of the container. These procedures appear to have the potential to allow users to inadvertently place a body part into the beam if sufficient controls are not provided to ensure that the device is in the fully shielding position at all times during the set-up.

Please provide sufficient instructions in any the procedures where the users will have the potential of placing any body part into the device beam area and the procedure should state that the users should lock the shutter in the closed position to ensure that the shutter can not be inadvertently opened during the implementation of these procedures.

Please demonstrate how the users are restricted by either physical or administrative procedural controls from inadvertently placing any body part into an open beam while performing installation, servicing, repairing, cleaning maintenance, leak testing, calibration and standardization procedures. In our opinion the device cage guard should be mandatory and not optional as indicated in your application.

- 13.6 Page 111 of the Instruction Manual refers to an "Operators Manual". Are these two distinct and different documents? Please explain the difference between the Instruction Manual and the Operators Manual.
- 13.7 Page 32 of the Instruction Manual states that proper operation of the shutter return requires correct pre-tensioning of the source return spring at installation. Please provide the functional and materials specifications of the spring . In addition, please provide a copy of the instructions and procedures to be used during installation, repair and routine maintenance of the C-frame device that addresses all necessary steps to be performed to ensure that the safety features and shielding of the device will function correctly and as a minimum include shutter movement, mechanical and electrical ON/OFF indicators, source return spring pre-tensioning, and verification of external radiation levels.
- 13.8 Page 111 of the Instruction Manual states "calls for an initial test of the 'BEAM OFF/BEAM ON' mechanism must be performed at the time of installation by authorized Scan Technologies personnel." Please note that these type of activities may only be performed by an individual specifically licensed by the NRC or an Agreement State. Please have the procedures and documents revised to reflect this requirement.
- 13.9 Please provide C-frame high tension holding down bolt mechanical and installation details. Would quarterly checks of C-frame support structure hold down bolts require any special tools?

13.10 On page 31 of the Manual, Step 8 provides instructions on how to remove the components that retain the source or sources. However, no instructions are provided on how to handle the source itself, when changing, and what radiation protection measures the operators must take. Please provide procedural steps for changing the sources including radiation protection measures.

14. QUALITY ASSURANCE

14.1 It is our understanding that C-frames are to be manufactured overseas. Please provide the quality assurance measures that will be taken to ensure the source holder configuration integrity on arrival in the USA.