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September 20, 2000

Mr. Tony Kirkwood (SSDR)
NRC
NMSS
Mail Stop T84
Washington, DC 20555-0001

RE: SSDR

Dear Tony:

Further to our recent telephone conversation concerning the ITI Qualitek Q200 Leakmeter. I am forwarding our original request for device registration, which was submitted in 1994. As you are aware our company was separated from Ion Track Instruments in January 2000 and documentation still overlaps both companies.

If you have any questions, or require any additional information, please do not hesitate to contact me.

Sincerely yours,

David Morris
President

MEGGITT CONTROLS

ION TRACK INSTRUMENTS INC

340 Fordham Road
Wilmington
Massachusetts
01887
USA
telephone
(508) 658-3767
fax
(508) 657-5954

March 21, 1994

Ms. Susan Greene
Medical, Academic and Commercial
Use Safety Branch
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Dear Ms. Greene:

RE: Request to add New Product to Ion Track Instruments Distribution License (No 20-15525-02E).

Ion Track Instruments requests that a new product, the Model 120-200 Leakmeter be added to its distribution license. This New Leakmeter is a direct decedent of an already existing product the Model 120 Leakmeter, which is currently on ITI's distribution License. The 120-200 Leakmeter uses the same radionulide activities at its predesesor Model and is acceptable in the construction of the ionization chamber from a health physics point of view.

To expedite the issue of a new license to ITI, I am providing you with a package of drawings and information for the Model 120-200 Leakmeter. I have highlighted the relevant area's that detail the ionization chamber and its labelling. An assembly drawing is also included detailing the outline of the product construction and the position of the detector assembly.

The main differences between the 120 and the 120-200 Leakmeter are:

A. Revised product packaging - the detector hand unit assembly is in essence the same for both units, the materials used in the 200 will offer additional strength to the unit.

B. The detector is mounted in both units at the front end of the hand unit assembly.

C. The software 120-200 Leakmeter has been completely revised to make the user interface much simpler.

D. Both ionization chambers are of similar construction with adequate wall thickness for shielding the ionizing radiation.

E. Both ionization detectors are assembled using a tamper proof locking system.

F. Both ionization detector assemblies contain a radioactive label which provides a caution and also denotes the activity of the source.

G. The radioactive source is identical in both units 10 mCi of ^{63} Ni β particles.

H. The detector assemblies used in the 120 & 120-200 Leakmeter are serialized sources from Amersham and or DuPont NEN. A detailed log is kept relating serial numbers of Leakmeters to serial number of the source used.

I. A wipe test of both products is actioned, after assembly and before shipment to our customer. The wipes are sent to a radiochemistry and health and physics facility for analysis.

J. Distribution from ITI is to both North and South America.

I trust the enclosures are sufficient to enable you to add the Leakmeter 120/200 to our current License. I would greatly appreciate if you would expedite the approval as soon as possible, so that we can continue selling the Leakmeter range into our established market base.

Sincerely yours,

William J. McGann
Director of R&D

WG/lam

Enc:

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May 12, 1995

Mr. Thomas W. Rich - Mechanical Engineer
Sealed Source Safety Section
Source Containment and Device Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
United States Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Rich:

In response to your letter dated 3/16/95 concerning our Model 120-200 Leakmeter. I am enclosing the additional information requested for you to complete the safety analysis of the device.

1. Method of attachment of the label is documented on the enclosed drawing A/200001-1 (Wire Attachment).

2. A copy of the prototype tests performed on the Model 120-200 Leakmeter is enclosed-reference Amershaw International QCS828 Issue 1.

3. QC Program - attached are the procedures used in the manufacturing and distribution of the device. Refer to documents 99106 and QCP No 130.

4. We are in the process of assembling the materials requested for the Model 120 Leakmeter. They will be forwarded to you in the near future.

I would very much appreciate a speedy response to our request for license for the Model 120-200 Leakmeter as this represents a major part of our business - We urgently need to resolve the issue to ensure our customers receive the latest in SF_6 detection (the Model 120-200 Leakmeter) as soon as possible.

I thank you in anticipation of a speedy response, please do not hesitate to call if require any additional information.

Sincerely yours,

David Morris
President

DM/lam

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September 27, 1994

U.S. Nuclear Regulatory Commission
Mr. Doug Brodus
Mail Stop T 8F5
11545 Rockville, Pike
Rockville, MD 20852

Dear Mr. Brodus:

In response to comments regarding the deficiencies in our application to add the Model 200 to our exempt distribution license.

First, pursuant to Section 32.26 (b2) the model number (manufacturer's number) of the ^{63}Ni foil sources are as follows. DuPont NER-0004 (370 MBq). This is a standard ionization source supplied by DuPont. (See Appendix D for Mfg. Specifications and registry of radio active sealed source).

Second, with regard to changes of physical/chemical form under operational conditions over the useful lifetime of the instrument, we can confidently report none. This is supported by the facts that we operate the ionization sources well within the manufacturer's specifications (see above) and that we have supplied of 5000 detectors of similar type around the world without an incident. Some of these systems have been in continuous (24 hr/day) operation for more than 10- years.

Third, pertaining to the solubility of the by product material in water and in bodily fluids, the following information is provided. DuPont performed a study several years ago when applying to register ^{63}Ni foils with the NRC. This study showed that the Ni foils are extremely pure and stable (negligible solubility) in water and bodily fluids. Over prolonged use of the foils, a thin nickel oxide layer forms over the surface. This NiO_2 layer is also insoluble in water and in bodily fluids. It was concluded in this report that even if the by-product material was ingested directly (an extremely unlikely if not virtually impossible event in our application) that the material would pass through the body with no biological half-life.

Fourth, pertaining to 32.26 (b5), the details of the construction and design of the product as related to containment, shielding and safety under normal and severe conditions of use, handling, storage and disposal, we are providing details regarding the materials of construction of the insulation cover and mounting insulator which houses and supports the ionization chamber. First it should be stated that these materials are in no way necessary for shielding. Furthermore, as stated in Section

32.26 (b12) regarding prototype testing of the Model 200 where the ionization chamber has been drop tested on its own and thermally cycled independently, these support materials are not required for safety in terms of leakage of by-product material under severe conditions. However, they because of their presence do provide an added measure of safety and definitely restrict the access of the ionization chamber. We have provided the details of the material used in the construction of Appendix A.

Fifth, pursuant to Section 32.26 (b6), the maximum external radiation levels at 5cm and 25cm from the external surface of the a product cannot be measured above the normal levels of backgound radiation. Effectively the emissions are "Zero".

Sixth, Pursuant to Section 32.26 (b7), regarding the degree of access of human beings to the product during normal use. Access to the ionization chamber in the Model 200 is first and foremost guarded by a tamperproof design. The dosimetry implications to humans in the actual handling of the ionization chamber is negligible. The only humans with cause to ever handle the ionization chamber will be production personnel and in-house service engineers. Users of the Model 200 will at no time access to the external housing of the ionization chamber and therefore dosimetry implications are also negligible.

Seventh, the maximum total quantity of by-product material expected to be shipped on an annual basis is 50 Model 200 units which represents 5000 millicurie of by-product material.

Eighth, pursuant to 32.26 (b9), the expected useful life of the product will be five years. The useful lifetime is in no way determined by the physical or chemical composition of the product itself as evidenced by the fact that some of our previous Models are still in use around the world after fifteen years.

Ninth, pursuant to Section 32.36 (b10), regarding labelling the point of sale package for the Model 200, we submit a detailed drawing of the point of sale label which will be affixed to each shipping case (See Appendix B).

Pursuant to Section 32.26 (b11), regarding procedures for prototype testing. We are now having test performed by Amersham International to establish a classification to ISO2919, and international standard for sealed radio active sources. This was apparently modelled on USA standard USAI N 5.10.

The classification being sought is C32211, the suggested level for chromatographic detectors. The initial "C" is determined by the toxicity of the radioactive material. The standard of test implied by the numbers are given in table 1 attached (copied from the identical British Standard). The two sheets give details of the experimental methods used.

These results take about 8 weeks to get back to Ai and I have placed a priority on them. However, they are not included in this package and will be forwarded as Appendix C as soon as we receive them. However suffice to say we do not expect any wipe to show greater than to 50 picoCuries of activity.

Pursuant to Section 32.26 (b13) - part a: regarding external radiation doses we respond as follows: Given the physical and chemical stability of the source, the typical operating conditions of the product, the accessibility of the ionization chamber and the tamperproof design of the ionization chamber itself, the estimated cumulative external radiation doses to any individual associated with building , distributing or servicing the product on an annual basis will far less than 5 millrem to any part of the body. The cumulative dose will fall into the low microrem range and will in fact be far less cumulative dose on the general population due to natural background radiation.

Part b: Regarding the likelihood of a significant reduction in the effectiveness of the containment or shielding from wear and normal use/abuse. The probability of exposure of any individual to the by-product material contained in the Model 200 over time due to reduction of effectiveness or integrity of the product is extremely low. The ionization source is both physically and chemically very stable. The ionization chamber is constructed from stainless steel and is of more than sufficient material thickness to be comprised by greatest amount of abuse. It is also a tamperproof design. Warnings, indicating the presence of a radioactive material are etched into the assembly.

In addition to the design features, we also rely on our historical record of distributing products of a similar nature containing the same by-product material for over fifteen years without a single incident. Over this period of time, more than 5000 such systems have been distributed and many of these systems operate continuously every day. One particularly relevant example is that we have distributed over 500 systems having a similar source assembly to virtually every nuclear power plant in the USA. These systems have an excellent record for reliability and our companies record for service and maintenance of our products in the field is second to none.

Part c: Regarding disposal of a single exempt unit or in storage of many such units, there is no risk of failure of confinement of the source or the shielding. Again, due to the extreme physical and chemical stability of the source and the construction of the ionization chamber the dose to any part of the body will not even begin to approach 1 millirem (See Appendix E - DuPont data sheets for ^{63}Ni).

Finally, Pursuant to Section 32.26 (b15) we have enclosed a copy of the quality control procedures for handling ^{63}Ni sources in our manufacturing facility. Additionally, once the product units have been manufactured, the final units are wipe tested over all outside sufaces for any residual contamination before they are distributed or put into inventory. (Appendix F contains the source handling procedures).

Sincerely yours,

Anthony Hawes
Ai Cambridge Ltd, (UK)
Development Manager

William McGann
Ion Track Instruments, Inc. (USA)
Director of R&D

Enciosures:

1. Table 1. Classification of Sealed Source
2. 200 Leakmeter Mechanical Testing
3. Appendix A - Materials used in Construction
4. Drawings - 200041 - A200001-1 - A00003 - 200008 - 200010 - 200011- 200017 200018 - 200027 - 200035 - 200039 - 200040 - 200062 - 200067 - 200091 - 200092 200097 - 91780 - 99024
5. Appendix B - Drawing 99065 - A200200
6. Appendix C - Results of Prototype Testing
7. Appendix D - Manufacturing Specifications and Registry of Radioactive Seal
8. Appendix E - DuPont Data Sheet
9. Appendix F - Source Handling