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

APR 1 1 2000

Mr. Thomas A. Kent
President
WEB Research, Co., Inc.
7317 Cahill Road, #251
Minneapolis, MN 55439

Dear Mr. Kent:

This letter is in response to your application dated October 18, 1999, requesting registration of the Model MSn9 Series Mossbauer sources, and to our telephone conversation on April 10, 2000, discussing your application. We are in the process of evaluating your request. However, in order to continue our review, the following information is necessary:

1. Your application indicates that there is a Co-57 version of the source. Please note that the Co-57 version of the source must be registered in the U.S. before it may be distributed in the U.S. This may either be submitted to the State regulatory body in the state where the U.S. distributor will reside (MN in the case of WEB Research), or in the case where both byproduct and accelerator-produced material will be registered in the same source, a combined registration may be issued by the NRC in non-Agreement States. If you intend to register the Co-57 source along with the Sn-119m source, please submit full information under separate cover letter to the NRC.

2. Your application indicates that you are considering this to be a doubly encapsulated source, with the first encapsulation being the ceramic matrix and the second being the welded source holder. Please note that the ceramic matrix does not constitute an encapsulation. As such, the NRC considers this a single encapsulated source.

3. Your application lists the principle use code for the source as "Foil Source (S)". We do not consider this a foil source, therefore please note that the principle use code will be listed on the registration certificate as "Other (T)".

4. As discussed with you during our telephone conversation on April 10, 2000, we will add the following statement to the Limitations section of your registration certificate. If there is a reason that this statement can not be added, please inform us immediately.

   "The sources will not be used with hazardous chemicals nor with materials that could detrimentally affect the integrity of the source holder, including cleaners."

5. Your draft registration certificate contained the following statement in the Limitations:

   "Decayed or unusable sources may be returned to the distributor or must be disposed of in accordance with the requirements of the Agency that maintains jurisdiction over the end user."

Our concern is with the first half of the statement regarding WEB Research taking back sources. Please note that the registration certificate and any instructions or materials that you provide your customers, must ensure that statements that do not constitute regulatory requirements are not inadvertently listed as regulatory requirements, nor listed in a way that may allow a user to assume that they are regulatory requirements. With respect to the statement listed above, you may inform your purchasers that you will take the sources back, however you must ensure that you do not present that information in such a way that it could be interpreted as a regulatory requirement (ex., listing it in the Limitations of the registration certificate, or listing it with a list of regulatory requirements such a leak testing). In light of this, we will not add the first half of statement as listed above to the Limitations of the registration certificate.

6. Please submit a drawing or picture of a typical Mossbauer spectroscopy set-up that the sources would be used in, including the drive unit.

7. Please provide a drawing and description of the lead storage containers, including dimensions, construction, and any other materials used.

8. The description lists a type 4 holder, but there is no type 4 on the chart. Please indicate whether you wish to register a type 4 holder. If you do, please provide dimensional information regarding the type 4.

9. You have provided drawings for the types 1 and 3 source holders. Please provide wall thickness of the holder components, as well as dimensions of the threaded end. Please provide complete drawings for the types 4, 5, and 6 source holders.

10. Your application references model numbers both as MSn9 (draft registration certificate page 1 and table in description) and Sn9 (description text and labeling example). Please clearly state the model number that you wish to register The model number should be consistent throughout.

11. Please further explain the model designation on the source holder labeling. The example used was Sn9.1.7.99, with the explanation of radionuclide symbol and chemical matrix symbol from Table 1, serial number, and 2 digit year. 99 is understood to be the year, and 7 is assumed to be the serial number. Please explain how the "Sn9.1" breaks down. Please note that the primary use of the labeling on the source is to allow reference back to the registration certificate where additional information can be gained. The proposed labeling would make it difficult to accomplish this since it does not directly relate to the model number as registered. Although there is no specific criteria for required labeling on the source itself, it is suggested that the source labeling more closely follow the model number as registered.

12. Please verify that you will provide radiation profile information to the user.

13. Regarding the source itself, since the source is not collimated, it is assumed that the maximum radiation profiles listed for the front of the source, apply to the 180 degrees in front of the source. Please either confirm, or provide correct profile information.

14. During our telephone conversation on April 10, 2000, you stated that there is some radiation scatter during source use due to sample material in front of the source, and estimated this to be approximately 0.2 mrem/hr at a couple of feet away. You also indicated that there is not a hazard to the user because the typical set-up shields the backscatter to the user. Please confirm this, or provide corrected information.

15. Your application states that although the standard loading activities will be 2, 5, 10, 15, and 20 millicuries, source loadings of up to 30 millicuries can be special ordered. Please note that you may not distribute sources that exceed the maximum activity listed at the front of the registration certificate. The maximum activity is the nominal plus upper range of the loading tolerance, which per your request will be listed as 30 millicuries total. Please indicate that you understand this requirement.

16. The prototype testing section of your draft registration certificate indicates activity testing error of up to 15%. The description section of your draft registration certificate indicates activities are nominal +/- 10%. Please provide the loading tolerance for the source activities, and explain the difference between the 10% and 15% values listed above. Your application states that the loading is "confirmed by substitution method using a reference source". Please explain this method.

17. Per your request, the maximum activity listed for you registration certificate will be 30 millicuries. Please clearly indicate how you will ensure that the sources do not exceed the maximum activity on the registration certificate, and the activity on the storage container.

18. Please indicate whether the activity on the source holder label and the lead storage container label is (a) the nominal activity, (b) the max (nom+10%), or (c) the actual measured? If it is the actual measured value, what is the error on the measurement?

19. Your quality assurance procedures describe the tests that will be done in the U.S. upon receipt of the sources from the Russian manufacturer. It is our understanding that these tests will be performed on a 100% basis (i.e., on all sources distributed). Please confirm.

20. During our telephone conversation, you indicated that, during your QC check in the U.S., the visual verification that the holder is correct type consists of generically checking the source holder size, using a rod to test the thread type, and verifying that there is no visible damage. Please confirm this, or provide corrected information.

21. During our telephone conversation, you indicated that, during your QA check in the U.S., you ensure matching information and consistency between the source holder, lead container, Ritverc documentation, and any U.S. QA tests performed. This should include isotope, activity, assay dates, model number, and serial number. Please verify that this is the case, or provide corrected information.

22. It is noted that the product is manufactured entirely in Russia, however, as the registered distributor, you are the entity responsible in the U.S. for ensuring that all sources distributed through your company have been manufactured in accordance with the materials submitted in support of the registration certificate. This includes being responsible for parts of the manufacturing performed in Russia. Ways of verifying the foreign manufacturer's process and procedures can include, but are not limited to, WEB Research quality control testing in the U.S., WEB Research physical audit of the quality assurance/quality control process of the manufacturer in Russia, third party audit of the manufacturer in Russia on behalf of WEB, or some combination of the three approaches. Please provide a complete description of how you will ensure that the sources have been manufactured in accordance with the drawings submitted, including inner and outer dimensions, wall-thickness, and materials. This should include all relevant receiving, in-process, and final product tests performed by the manufacturer.

23. Your application states that the prototype testing was done in accordance with GOST 25926-90, however, your draft registration certificate states that the tests were done in accordance with ISO 2919. Please clearly indicate what standard the tests were conducted in accordance with. If they were conducted in accordance with GOST 25926-90 standard, please provide an English translation of the standard so that we may complete our evaluation of your prototype testing.

24. The prototype testing information indicates that Co-57 versions of the sources were tested. Please provide additional information that demonstrates that testing of the Co-57 sources adequately substitutes for testing of the Sn-119m sources. This includes information demonstrating that the difference radioactive material form would not adversely affect the test results if the Sn-119m ceramic matrix was tested instead of the Co-57 metal form. It is understood that the source holders used for the Co-57 and Sn-119m sources would be identical, however, from the information submitted, it was not clear which source holder type was tested. Please clearly identify the source holder type, or types, tested, and demonstrate that the based on those holders tested, that the untested holders would pass the prototype testing.

Please provide the requested information within thirty (30) days of the date of this letter. If you have any questions, please contact me at (301) 415-5868 or Seung Lee at (301) 415-5787.

Sincerely,

Michele L. Burgess

Michele L. Burgess, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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Michele L. Burgess, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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