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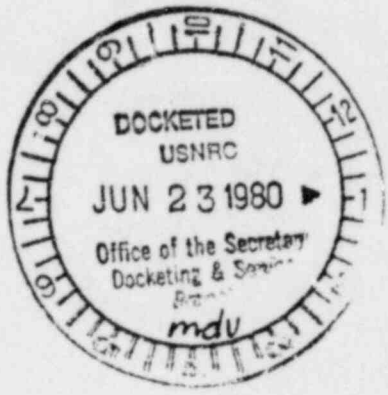

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Attn: Docketing & Service Branch
Washington, D. C. 20555

SEARLE

Dear Sir:

This letter is to comment on the advance notice of rule making on certification of personnel dosimetry processors published in the March 28, 1980 Federal Register.

On May 23, 1980 Searle Health Physics Services was acquired by Siemens. Our new name is Siemens Gammasonics, Inc., Health Physics Services.

We do not believe that the recent pilot study conducted by the University of Michigan accurately reflects the capabilities of all processors. This test was conducted using a new standard. It was also conducted using a standard which was subject to change at the time of the pilot study and which is still subject to change today. Although we expended a great deal of effort in participating in the pilot study and attempting to adapt to the new standard, we did not make the large capital expenditures for new sources and other equipment which we knew would be necessary to meet some parts of the standard because the standard was still subject to change. On June 4, 1980 we requested a copy of the latest version of the standard from Dr. Margaret Ehrlich. This request was denied. Dr. Ehrlich stated that the latest revision would not be released for six to eight weeks. We believe that it is extremely important that the Nuclear Regulatory Commission (NRC) finalize the standard as quickly as possible to insure that the processors have the necessary time to adapt to the new standard.

We believe that the clerical errors which occurred during the pilot study do not reflect the typical performance of large commercial processors. Because the pilot study

required evaluation techniques different than those currently in use, the evaluation and reporting of dosimeters used in the pilot study was done manually by laboratory personnel. Evaluation of dosimeters for clients is done using automated techniques incorporating sophisticated methods to prevent data handling errors.

At the time the pilot study was announced its purpose was to test the adequacy and feasibility of the proposed ANSI N13.11 standard. The pilot study was not a test of the accuracy of the service dosimetry processors are providing now.

It is probably true that some small processors are not technically competent to provide reasonably accurate dosimetry to their employees or clients. It is probably also true that these processors are serving radiation workers whose exposure is very low. This suggests that the public health benefits derived from a testing program may be small.

We estimate that the initial capital investment necessary for Siemens to change from current calibration methods to the proposed ANSI N13.11 will exceed $200,000.00. The annual cost of participating in the testing program will be $50,000.00. None of this money will be spent on improved quality control equipment or procedures.

These expenditures will raise the cost of dosimetry service. Since most radiation workers are in the health care industry, an increase in the cost of health care will result. Will the proposed certification program produce the greatest improvement in the public health per dollar spent, or would greater benefit be realized if the money were spent in some other way?

If a certification program is implemented we believe that it can best be accomplished by establishing a certification program that would require dosimetry processors to pass one test per year based on the proposed ANSI standard N13.11. This would demonstrate that the processor has the necessary

technical competence to develop and operate an adequate dosimetry system.

We do not believe the certification program should prohibit a processor from providing dosimetry service to a client based on calibration factors or sources other than those specified in the standard. If the radiation exposure received by a client's employees comes from sources other than those specified in the standard, more accurate dosimetry would result from calibrations based on the sources being used.

We believe a certification program will be ineffective if it is not adopted by all applicable regulatory agencies. U. S. Nuclear Regulatory Commission regulations apply to a small fraction of the total radiation workers in the United States. If the accuracy of personnel dosimetry needs to be improved, it needs to be improved for everyone. If a certification program is established and it is only adopted by the Nuclear Regulatory Commission, we believe that the result will be the establishment of two different levels of commercial dosimetry service: one which meets the certification requirements which will be used by NRC licensees and another less expensive service which will be used by most other radiation workers. The market for dosimetry service for radiation workers not covered by NRC regulations is so large that a processor could elect to serve this market only and escape any testing.

The method used to publish the results of the certification tests is extremely important to commercial dosimetry services. If we assume that the certification program is adopted by all federal regulatory agencies, certification will then be necessary for commercial dosimetry services to stay in business.

Radiation dosimetry is a very complex process. It is probable that most processors will fail some part of the test at some time. We believe that procedures to allow a processor to be retested must be included in the

regulations. The results of any test failed by a processor must not be published until the retest procedure has been exhausted.

We believe the regulations must include a review committee composed of members involved in personnel dosimetry. Disputes between processors and the testing laboratory will occur. It is also possible that a processor may encounter a problem that cannot be corrected within the time allowed by the regulations due to circumstances beyond the control of the processor. The review committee would provide an appeal process to handle these situations.

We do not believe the review committee should consist of representatives of one or more regulatory agencies. It is important that the members of the review committee have detailed technical and practical experience in personnel dosimetry. This expertise does not exist within the regulatory agencies. Regulatory agencies should be allowed to have observers present at review committee proceedings, but should not take part in the decision process.

It is not clear how the decertification process would function with respect to commercial processors. The commercial dosimetry industry is an oligopoly dominated by one firm with nearly 50% of the market. If that processor was decertified it would be impossible for several hundred thousand radiation workers to obtain certified dosimetry service. If one processor is effectively immune to decertification, what about the other commercial processors?

We believe a single private testing laboratory under contract to the National Bureau of Standards (NBS) should conduct the certification tests. NBS is the most technically qualified agency to oversee the operation of the testing laboratory and should be the contractor.

The testing laboratory must be willing and able to provide technical services in addition to the actual certification tests. Processors will require intercomparisons with their own calibration facilities and special exposures to help calibrate new dosimeters or solve special problems. We believe a private laboratory will be better able to

provide these services at reasonable cost than a government laboratory.

If a dosimetry testing program is necessary we believe the following steps must be taken:

1. Finalize and publish the standard to be used.

2. Obtain the concurrence of all federal regulatory agencies.

3. Define and publish detailed regulations and procedures for the operation of the certification and decertification process.

4. Select the testing laboratory.

5. Start the mandatory testing program. During the first 18 months results should not be published and processors should not be decertifed. This will provide adequate time for all processors to adapt to the new standard.

6. Start publication of results and decertification proceedings.

Thank you for your consideration of these comments.

Sincere[illegible],

William E. Todd
Manager
Health Physics Services

WET/k