DAYBREAK NUCLEAR AND MEDICAL SYSTEMS, INC.

Ms. Glenda Jackson
Senior Policy Analyst
License Fee and Debt Collection Branch
USNRC
Washington, DC 20555

4 March 1993

Dear Ms. Jackson;

Having received your letter dated 1 March kindly listing fees paid and refunds made by the USNRC, I find that some of my recollections as recounted to Ms. Sandra Kimberley last December were in error, and I am enclosing checks to cover the difference in renewal fees and the 1991 annual fee.* I do intend, however, to pursue a change in my license in order to have it read "irradiation of materials" instead of "measurement of materials", since this is the actual intention scientifically for the technique I employ, and it seems clear to me from my license applications and all supportive material that this should be so. In fact, my request for a reclassification was granted by the Region I licensing people in a letter dated 3 December 1991. I have been operating under the assumption that commonsense would prevail in this case eventually, even though someone in Washington (your office?) apparently later told Region I to keep out of it.

In reviewing my license, in particular the 1987 renewal and the "corrected copy" of 3 December 1991, I find that no changes were made at all in the authorized use. I had discussed changes to be made by phone with them at length; they agreed with my reasoning, and changed the programming code to 3E. I believe that the changes that the Region I licensing people had intended, to make the 3E fee category appropriate, were inadvertently left out. This may in fact be the source of all the confusion.

Just in case your impression might have been that a grant of a change in fee category would lead to a stampede of similar licensees seeking the same, I believe that I am the only licensee under NRC jurisdiction working in TL dating with a specific license, rather than a broad license.

Certainly, in the past the difference in fees between the categories was negligible, but now the fee for inspections between 3P (a catch-all category including all the "difficult" situations) and 3E exceeds $800. I know that with my two sealed sources, housed in

* sent separately to Ms. Kimberley, per your instructions.

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irradiators where the sources are not removed from their shields, the actual inspection time related to my radiation safety program did not exceed 45 minutes, and the remainder was devoted to a discussion of other matters. These included discussion of irradiators, vis a vis my license, and other topics including reminiscences about acquaintances in common, to fill in some time before Duncan White's next scheduled appointment. Even with some paperwork at the home office, $1300 seems unjustified. This in itself suggests that the fee category is inappropriate, when for a little more I could be inspected as a manufacturer or broadly licensed user, rather than a user of sealed sources (that are not used as an integral part of a measurement apparatus, but serve in a way analogous to check sources) in very safe shielded irradiators, and one wipe test standard. Since fee category 3E fits the application, and was the original intent when I first applied for my license in 1977 (The irradiators I used were designed with this in mind, in consultation with the person in the licensing division handling the application, Earl Wright), it makes sense that the license category should be changed In fact, since the NRC never actually informed me of a fee category, I assumed in good faith that it was 3E, and paid the renewal fees accordingly. Now, since I do not handle the book keeping, I was not aware of the refunds made, and there was apparently no correspondance with it.

Parenthetically, it might be useful to put the fee category on the license itself (it is nowhere stated), and include criteria for inclusion in a particular category, so that licensees could petition for a change if they considered it justified, and not get sandbagged, as I was.

As far as additional fees for device review pertaining to the 1100 automated TL measurement system, I should like to inform you that this is not a device that contains radioactive material, nor is intended to incorporate a sealed source. The intent was to have the option of placing my present irradiator, or one of the same design, on top of it, using the mechanism of the 1100 as a sample changer. At present the irradiator is placed on a metal plate that centers the sample to be irradiated; in the license application, the use originally specified was using the irradiator atop the TL glow oven, the configuration of which was never specified, nor was I asked to provide detailed drawings. My interpretation of this is that the irradiator may be used on a TL glow oven or such other fixture as may hold the sample, whether it is my original glow oven, long since junked, or a replacement, which includes the 1100. If one takes the logic behind a request to evaluate the 1100 as a device one step further, I should be asked to pay $1700 for an evaluation of the lab bench the irradiator sits on. I enclose a copy of the relevant parts of my original application (carried over into subsequent renewals) for your information, not because your office has any jurisdiction regarding licensing matters, but because I wish to convey to you the fact that my reasoning is no stretch of fact or interpretation. I likewise make the interpretation that building a second irradiator identical to the first would not require an evaluation. To require it would be serve little purpose beyond raising revenue. I therefore decline to pay this evaluation fee without further discussion with the licensing people, and the application timely submitted last year may be revised so as to

ensure reclassification and no imposition of further fees.

In regard to commercial production of irradiators, my comments largely concern applicability of 10 CFR 32.210 and NRC jurisdiction. First of all, I do not (as Daybreak Nuclear or personally) manufacture nor am I first distributor of any sealed source or device containing a sealed source; I do not intend to do so. I do manufacture devices that the customer may load with sealed sources himself, at his pleasure. Secondly, the greater part of my business is for export, and in the past 14 years, only one device (in 1982) came under NRC jurisdiction as a specifically licensed item. If the solution is to decline sales to any entities where a device review is necessary, then so be it. I can make drawings of the devices public domain. A registration fee of $3500/device where there are five variations, each selling worldwide at no more than one/year at at price of $600-800 is not affordable, nor within the realm of financial prudence for my size company. My specialized market is very small. Back in 1982, the last time (and only time before now) I was asked about device registration, the NRC opinion (given informally) was that the quantity was too low to justify registration, and characterization as a custom device was justifiable. One of the topics covered during my last inspection, in December, was this. In a review of all devices sold domestically since 1979 when I commenced manufacturing of TL instruments, NRC jurisdiction was found only for the one mentioned above. Also, during that period of time, these devices have undergone considerable evolution, and customizing for particular customers, with certain parts remaining standard. In light of the President's stated aim to have government encourage business, I believe that the continuation of a policy holding these devices to be custom-made would be appropriate.

While this is not the place, nor my intent here, to criticize your fee structure, the need for which was imposed upon you by Congress, I would like to state that the annual fees and large flat inspection fees are an onerous burden upon the small business licensee. I am literally a "mom and pop" operation. I, personally, am the licensee rather than my little corporation, so I naturally take all of this rather to heart. The invoice for the FY1991 annual fee came the first month ever I could not pay my mortgage. I think that the people in Washington have not been truly aware of real life conditions in recent years.

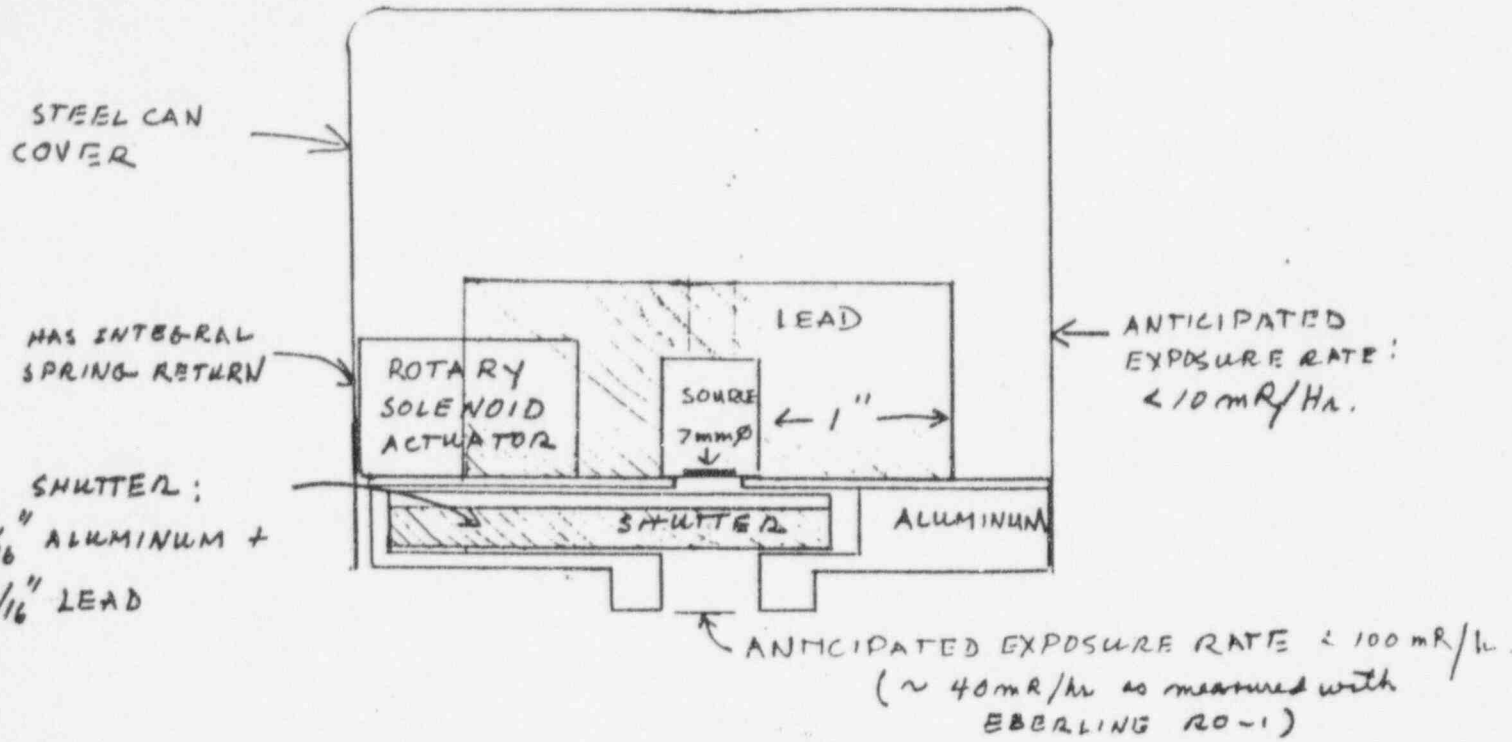
Although I am paying fees as stated above, I do intend to pursue the change in category, a change retroactive at least to FY1991. In doing so, I will be requesting a refund of these fees, which are being paid solely to keep my license from expiring.

I honestly have no axe to grind with the NRC beyond this question of fee category; I believe that in general you are doing a fine job. However, I do feel that like most government organizations, the NRC is not very efficient, resulting in excessive expenditure for the work accomplished. It comes as a shock when I have to pay for it.

Sincerely yours,

Victor J. Bortolot, Ph. D.

cc: Commissioner Gail de Plangue
Jenny Johansen, Region I
Duncan White, Region I



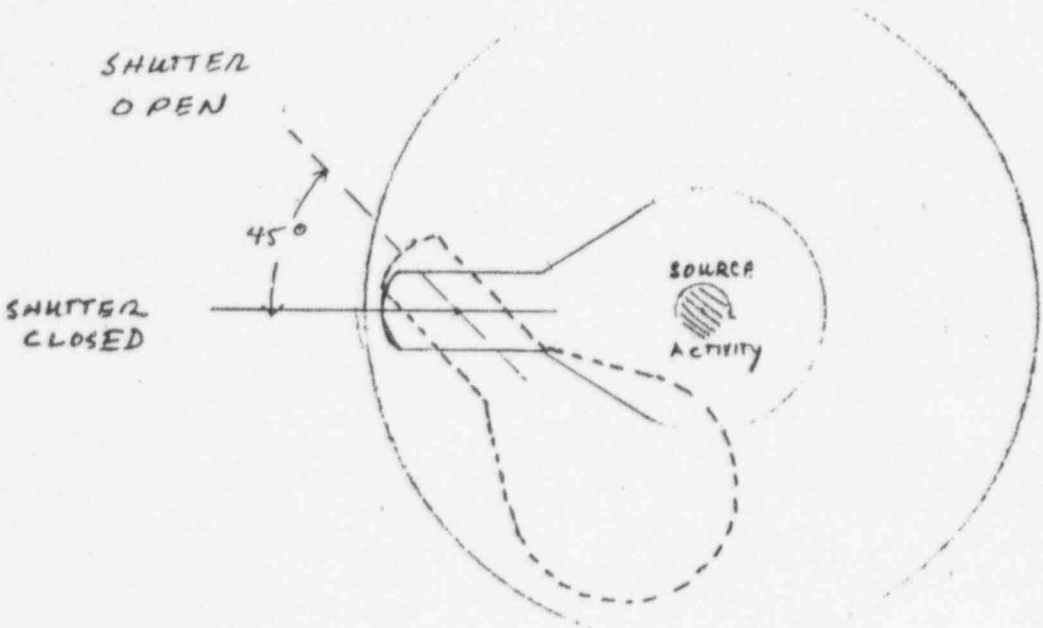


FIGURE 2. Sr^{90} SHIELDED EXPOSURE DEVICE, ACTUAL SIZE.

WHEN NOT IN USE, DEVICE WILL SIT ON 2" LEAD BRICK.

WHEN IN USE, DEVICE WILL SIT ON TL READOUT OVEN (~ 1" ALUMINUM).

from 1977 application or subsequent renewals

ITEM 9. Source storage.

(1) The Am-241 sealed source is housed and used in the device shown in Figure 1. This has an electrically-operated (solenoid) arm with a fail-safe spring return that carries the source out of the housing over the sample to be irradiated. At all times the active surface of the source is inaccessible to human contact. By use of an alpha absorber, the gamma component alone is available for use as a calibrator for TL personel monitor badges. This source has been standardized against radium using the same TLD material.

(2) The Sr-90 sealed source is stored and used in the shielded device shown in Figure 2. This, like the alpha housing above, is electrically operated. The spring return shutter protects the source against mechanical damage and human contact. When the solenoid is not energized, the shutter remains closed in all orientations, and cannot be opened without dissassembly of the device. The shutter is a composite of 1/16" aluminum alloy and 3/16" lead to minimize brehmstrahlung production. As measured with an Eberline RO-1 ionization type survey meter, the closed shutter exit exposure rate is 45 mR/hr and the surface exposure rate on the steel enclosure can is about 10 mR/hr. The device is stored in a fireproof safe on and behind lead brick. In use, the device is placed 2 feet from the TL reader on and behind lead brick. When a sample calibration* is to be done, the device is placed on the TL reader glow oven directly over the sample, and the shutter opened by an electronic timer. The exposure on the under surface of the glow oven during irradiations is 20 mR/hr. The source is in use about 200 hours annually. Dose monitoring of the applicant has shown less than 250 mR exposure per year during the term of the current license.

*this wording is loose, and scientifically incorrect, but in 1977, it didn't matter.