

# DAYBREAK NUCLEAR AND MEDICAL SYSTEMS, INC.

8 March 1993

Dear Ms. Kimberley;

I am enclosing a check for a total of \$451.53, covering the residue of invoice AM1046-2 plus renewal license fees. This should keep the federal marshalls from carrying me off in chains. However, I consider this to be a strategic retreat, and will renew my efforts to get my license fee category changed to the one I feel is appropriate for my activities.

Yours, till next time,



Victor J. Bortolot, Ph.D.  
Technical Director.

01-01-17 11:11:13

50 Denison Drive Guilford, CT 06437

(203) 453-3299

9701310293 920612

PDR RC \* PDR  
SSD

# REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

Instructions: Send this request AND a copy of all related letters/applications and drawings to:  
The Sealed Source Safety Section, ATTN: Steven Baggett, ONFH Mail Stop 6-H-3.  
Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.  
NOTE: Retain a copy of this request with the application and background files.

REQUESTOR: Sandra Kimberly  
PHONE NO.: 491-8743  
APPLICANT'S NAME: Bartolet, Ph.D., Victor  
MAIL CONTROL NO.(S): 116381

REGION: I II III IV V, HQ or LFDCB  
DATE: 4-7-92  
LETTER/APPLICATION DATE: 3-20-91  
LICENSE NO.(S): 06-17253-01

TYPE OF ACTION REQUESTED (CHECK APPROPRIATE ACTION(S))

( ) SOURCE REVIEW (X) DEVICE REVIEW ( ) CUSTOM REVIEW  
( ) AMENDMENT OF REGISTRATION SHEET NO.(S) \_\_\_\_\_

COMMENTS: \_\_\_\_\_

## FOR SSSS USE ONLY

DATE RECEIVED: 7-1-92 ASSIGNED NO.: 92-42  
MODEL NUMBERS: 1102  
REVIEWER: \_\_\_\_\_

DATE TO FEES: 7-15-92

DATE ASSIGNED: \_\_\_\_\_

TYPE OF ACTION (INDICATE NUMBER OF EACH TYPE)

- ( ) COMMERCIAL DISTRIBUTION (FORMAL)  
SOURCE (9C) DEVICE (9A)  
NEW NEW  
AMENDMENT AMENDMENT  
( ) USE BY A SINGLE APPLICANT (CUSTOM)  
SOURCE (9D) DEVICE (9B)  
NEW NEW  
AMENDMENT AMENDMENT  
( ) NO SAFETY EVALUATION REQUIRED - NO FEES REQUIRED  
( ) LICENSING ACTION REQUIRED IS KNOWN: YES / NO  
( ) OTHER: \_\_\_\_\_

Do Not Issue.  
Fees NOT  
Collected for  
Anything as  
of yet. S. Kimberly  
he SSSSDS.

TOTAL NUMBER OF REVIEWER HOURS: \_\_\_\_\_

NUMBER OF DEFICIENCY LETTERS: \_\_\_\_\_

NUMBER OF DEFICIENCY CALLS: \_\_\_\_\_

NOTES: \_\_\_\_\_

## FOR BILLING PURPOSES ONLY

( ) NAME CHANGE ( ) ADDRESS CHANGE (X) NEW REGISTRATION - ADD TO BILLING  
( ) PRODUCT INACTIVE - REMOVE FROM BILLING

## FOR FEE USE ONLY

TYPE OF FEE: \_\_\_\_\_  
AMOUNT RECEIVED: \_\_\_\_\_  
DATE OF CHECK: \_\_\_\_\_  
APPROVED BY: \_\_\_\_\_

FEE CATEGORY: 9A 9B 9C 9D  
CHECK NUMBER: \_\_\_\_\_  
LOG: \_\_\_\_\_  
DATE RETURN: \_\_\_\_\_  
DATE: \_\_\_\_\_

( ) MATAMN UPDATED  
AS REQUIRED  
( ) MATSYS UPDATED  
AS REQUIRED

COMMENTS: \_\_\_\_\_

# INDIVIDUAL SSD CASE STATUS

ASSIGNED #: \_\_\_\_\_  
 REVIEWER: \_\_\_\_\_  
 DATE ASSIGNED: \_\_\_\_\_  
 MAIL CONTROL #: \_\_\_\_\_

MANUFACTURER: \_\_\_\_\_  
 MODEL #: \_\_\_\_\_  
 CONTACT: \_\_\_\_\_  
 PHONE NUMBER: \_\_\_\_\_

FOR THE FOLLOWING, ENTER DATE OF COMPLETION, OR EXPLAIN DEFICIENCIES.

	DATE	EXPLANATION
PAGE HEADING:	_____	_____
COVER PAGE:	_____	_____
DESCRIPTION:	_____	_____
LABELING:	_____	_____
DIAGRAM:	_____	_____
CONDITIONS:	_____	_____
PROTOTYPE TESTING:	_____	_____
EXT. RAD. LEVELS:	_____	_____
QA/QC:	_____	_____
LIMITATIONS:	_____	_____
SAFETY ANALYSIS:	_____	_____
REFERENCES:	_____	_____

	PHONE	LETTER
DEFICIENCY 1:	_____	_____
DEFICIENCY 2:	_____	_____
DEFICIENCY 3:	_____	_____
DEFICIENCY 4:	_____	_____

SPELL CHECK: \_\_\_\_\_  
 1ST. DRAFT: \_\_\_\_\_  
 2ND. DRAFT: \_\_\_\_\_  
 COMPLETED: \_\_\_\_\_  
 COMP. LETTER: \_\_\_\_\_

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PHONE NO.: 492-8743  
APPLICANT'S NAME: Bartolot, Ph.D., Victor  
MAIL CONTROL NO.(S): 116381

REGION: 1 II III IV V, HQ or LFDCB  
DATE: 4/7/92  
LETTER/APPLICATION DATE: 3/20/92  
LICENSE NO.(S): 06-17253-01

TYPE OF ACTION REQUESTED (CHECK APPROPRIATE ACTION(S))

- ( ) SOURCE VIEW ( ) DEVICE REVIEW ( ) CUSTOM REVIEW  
( ) AMENDMENT OF REGISTRATION SHEET NO.(S)

COMMENTS: Is license listed as "custom" device? Is the device used as we define irradiators' use? Is the app. a change to the original device?

FOR SSSS USE ONLY

DATE RECEIVED: 4/23/92 ASSIGNED NO.: \_\_\_\_\_ DATE TO FEES: \_\_\_\_\_  
MODEL NUMBERS: \_\_\_\_\_  
REVIEWER: Doug Broadus DATE ASSIGNED: Steve

TYPE OF ACTION (INDICATE NUMBER OF EACH TYPE)

- ( ) COMMERCIAL DISTRIBUTION (FORMAL)  
SOURCE (9C) DEVICE (9A)  
NEW NEW  
AMENDMENT AMENDMENT  
( ) USE BY A SINGLE APPLICANT (CUSTOM)  
SOURCE (9D) DEVICE (9B)  
NEW NEW  
AMENDMENT AMENDMENT

(X) NO SAFETY EVALUATION REQUIRED - NO FEES REQUIRED - No distribution

( ) LICENSING ACTION REQUIRED IS KNOWN: YES / NO

( ) OTHER: \_\_\_\_\_

Per your 6/23 conversation with Duncan White, here is the pkg. to determine whether or not licensee is distributing devices he has in poss., need to be registered, does Detroit have custom registration & why are some being distributed, if they are. Thanks

TOTAL NUMBER OF REVIEWER HOURS: \_\_\_\_\_

NUMBER OF DEFICIENCY LETTERS: \_\_\_\_\_

NUMBER OF DEFICIENCY CALLS: \_\_\_\_\_

NOTES: ALSO

Does he set up these machines at the places that have them? (if places have them)

FOR BILLING PURPOSES ONLY

- ( ) NAME CHANGE ( ) ADDRESS CHANGE ( ) NEW REGISTRATION - ADD TO BILLING  
( ) PRODUCT INACTIVE - REMOVE FROM BILLING

MANUFACTURER/DISTRIBUTOR: \_\_\_\_\_

REGISTRATION #: \_\_\_\_\_

MODEL #: \_\_\_\_\_

REFERENCES: \_\_\_\_\_

DESCRIPTION	OK/DEF (✓/D - PESP DATE)	COMMENTS
FIRST PAGE		
Registrant's Name and Address		
Manufacturer's and Distributor's Name and Address		
Custom User's Name and Address		
Device Model Number		
Device Type		
User's Authority to Possess (general, specific, exempt)		
Radionuclides, Activity (Max w/% error), Form, Manufacturer, Model, NRC Registered		
DESCRIPTION		
Device/Source Design with Complete Engineering Drawings (dimensions, tolerances, list of materials)		
Assembly Methods (screw, welds, etc.)		
Source Mounting (size and integrity) and Security		
Is Source ANSI Classification Sufficient: Radiography - Unprotected - 43515 Radiography - In Device - 43313 Medical - Radiography - 32312 Medical - $\gamma$ Teletherapy - 53524 $\gamma$ Gauges - Unprotected - 43333 $\gamma$ Gauges - In Device - 43232 $\beta$ Gauges, Low Energy $\gamma$ Gauges, or X-ray fluor - 33222 Oil Well Logging - 56522 Portable Moist/Density - 43333 Neutron Applications - 43323 $\gamma$ Irradiators (II, III, IV) - 43424 $\gamma$ Irradiators (I) - 43323 Chromatography - 32211 Static Eliminators - 22222 Smoke Detectors - 32222		
Definition of Shutter Operation		
On-Off Indicator (lock in Off, not in On)		
Safety Interlocks, Guards, etc. to prevent access to beam or high radiation levels		
Depleted Uranium Corrodes with Steel (copper/zinc as separator)		
Corrosion between Aluminum and Steel		



DESCRIPTION	OK/DEF (✓/D - RESP DATE)	COMMENTS
Well Logging sources must be nondispersible and nonsoluble		
Radiography Cameras/Sources per Part 34 checklist		
<b>RADIATION PROFILES</b>		6
Survey Instrument Used (type, window, sensitivity, etc.)		
Conditions		
Distance from Source/Surface		
Shutter On and Off/Source Shielded		
Scatter (product in beam)		
Guards and Shields in Place		
<b>INSTALLATION</b>		
Fixed, Portable, Movable, Fixed Installation but portable source housing		
Inherent Shielding, Inaccessibility		
Interlocks, Locks, Barriers		
Be Access: Size of Air Gap/Opening to Beam		
Mounting Integrity		
<b>PROTOTYPE TESTING</b>		
Tests Methods and Conditions (for source and device)		
Tests Results		
Years of Use (incidents, failures, etc.)		
<b>QUALITY ASSURANCE</b>		
Materials, Subassemblies, Services		
Assembly Methods (screws, welding, etc.)		
Dimensions and Tolerances		
Activity, Radiation Levels, Leak Tests		
QA Manual		
<b>LABELING</b>		
Copy of Label		
Materials, Dimensions, Colors		
Permanent Attachment and Location		

DESCRIPTION	OK/DEF (✓/D - RESP DATE)	COMMENTS
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)		
SAFETY INSTRUCTIONS		
Operation, Maintenance, Calibration, Damage/Failure, Specific Warnings, Leak Test, and Radiation Surveys		
ACCOMPANYING DOCUMENTATION		
Leak Tests Results and Radiation Surveys		
Transportation Documents		
Operation, Maintenance, Calibration, Damage/Failure, Specific Warnings, Leak Test, and Radiation Survey Instructions if Applicable		
SERVICING		
Manufacturer Provides or User Performs: Installation                      Calibration Relocation                      Leak Test Maintenance                      Radiation Survey Repair                      Training Source Change/Installation		
FOREIGN MANUFACTURERS		
Drop Ship		
Who and Where is Source Installed		
Leak Test and Radiation Surveys		
QA in the U.S.		

GC = all acceptable changes?

Radiation - all complete sources & things

Limit of 500 lbs

500 Limit - <sup>operation & status</sup> must be checked & fixed or some remedy about action being taken