



July 18, 2012

Director, Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

SUBJECT: REQUEST FOR EXTENSION OF AUTHORIZATION FOR LIMITED SHIPMENTS AOS 5979,
TYPE B PACKAGE, USA/5979/B ().

DOCKET: 71-9316, 71-5959

TAC No: LA-0129

Mr. Saverot,

In response to your email dated 25JUN12 requesting, under oath and affirmation, the information requested in paragraph 3(c) of the RIS, to include end-user justification of any shipment and the specific impacts of not receiving a planned shipment before December 31, 2012.

1. Cleveland Clinic Foundation
 - 1.1. No rescheduling is possible due to the unavailability of foreign sources and packaging during the scheduled time frame.
 - 1.2. Will require an AOS Export License amendment to dispose of spent sources.
 - 1.3. See attached end-user statement.

2. Akron General Medical Center
 - 2.1. No rescheduling is possible due to the unavailability of foreign sources and packaging during the scheduled time frame.
 - 2.2. See attached end-user statement.

3. University of Minnesota – Fairview
 - 3.1. No rescheduling is possible due to the unavailability of foreign sources and packaging during the scheduled time frame.
 - 3.2. Will require an AOS Export License amendment to dispose of spent sources.
 - 3.3. See attached end-user statement.

4. Barrow Neurological Institute | St. Joseph
 - 4.1. No rescheduling is possible due to the unavailability of foreign sources and packaging during the scheduled time frame.

NIMSS01

4.2. Will require end-user license amendment to allow the use of foreign sources.

4.3. Will require an AOS Export License amendment to dispose of spent sources.

4.4. See attached end-user statement.

5. UCSF

5.1. No rescheduling is possible due to the unavailability of foreign sources and packaging during the scheduled time frame.

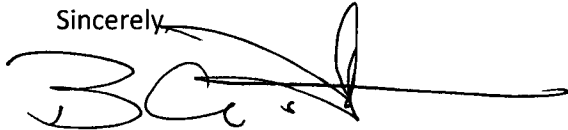
5.2. Will require an AOS Export License amendment to dispose of spent sources.

5.3. See attached end-user statement.

If you have any questions concerning this request, please contact me at (562) 804-0604 or brobnett@alpha-omegaserv.com. Thank you for your consideration.

I affirm under oath that the above statements and the attached information, both of which were provided by the end-users, are true to the best of my knowledge.

Sincerely,

A handwritten signature in black ink, appearing to read 'B. Robnett', with a long horizontal stroke extending to the right.

Bob A. Robnett
Director Operations & Regulatory Affairs
Alpha-Omega Services, Inc.
9156 Rose St
Bellflower, CA 90706

Enclosures: 5

Please see Attached for
CA Gov't Code 8202
Compliant Jurat

Jurat

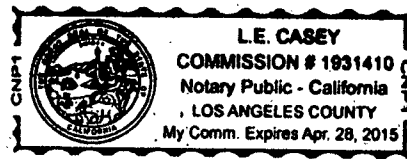
State of California)

County of Los Angeles)

Subscribed and sworn to (or affirmed) before me on this 18th day of July, 2012,

by Bob A. Robnett
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

L. E. Casey (Seal)
Signature of Notary Public



Description of Document

Title: Letter: Request for Extension of Authorization For Limited

Shipments ...

Containing 2 Pages 1 Sides, and Dated: July 18th, 2012

06/27/2012

Elekta, Inc.
4775 Peachtree Industrial Blvd., Building 300, Ste. 300
Norcross, GA 30092

Dear Sirs:

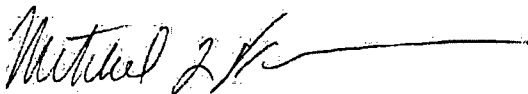
It is my understanding that the NRC proposes to postpone for a significant length of time, delivery of the Cobalt-60 sources required to treat patients on our Gamma Knife unit.

These sources are not a replacement for ones on an already existing unit, wherein delivery delay would result only in longer treatment times for patients. The sources are required for the operation of a newly installed Gamma Knife, and therefore any delay in delivery would result in either patients not receiving treatment or, of necessity, having to travel a long distance to receive treatment.

Additionally, Elekta has already scheduled blocks of time for on site staff training with the fully installed unit. Individuals have been hired in anticipation of this, and a delay in delivery of the sources would result in their being idle unnecessarily.

I respectfully request that the NRC reconsider its plan to delay delivery of the Cobalt-60 sources for the Akron General Medical Center Gamma Knife because it would impose significant hardship on patients and staff.

Sincerely,



Mitchel L. Fromm, MD
Chairman, Department of Radiation Oncology
Akron General Medical Center
400 Wabash Avenue
Akron, OH 44307



Gene H. Barnett, M.D., MBA, F.A.A.N.S., F.A.C.S
Rose Ella Burkhardt Chair in Neurosurgical Oncology
Professor & Director,
Rose Ella Burkhardt Brain Tumor & Neuro-Oncology Ctr

June 27, 2012

Nuclear Regulatory Commission

To Whom It May Concern:

The Perfexion Gamma Knife Unit located at the Cleveland Clinic Gamma Knife Center has a planned source replacement from 7/3/2012 – 8/1/2012. At this time our Cobalt 60 Radiation Source has reached its half-life and needs to be replaced. This project was been planned and in progress for almost a year now.

Currently we are continuing to treat patient but since the source has reached its half-life, treatment times have been prolonged. These lengthened treatments times cause a great deal of dissatisfaction for our patients who now remain in the unit and attached to the head frame, for longer periods of time. In addition to longer treatment times and lengthen work days, the number of patients that can be treated each day has decreased, thereby causing delays in patient treatments.

Delaying the source replacement will cause unnecessary delays in patient treatment which will compromise the quality of patient care. In our opinion it is essential to patient care and operational efficiency for the source replacement to occur as planned in the month of July, 2012.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gene Barnett', with a long horizontal stroke extending to the right.

Gene Barnett, MD



**St. Joseph's Hospital
and Medical Center**

A Dignity Health Member

St. Joseph's Hospital and Medical Center
350 West Thomas Road
Phoenix, AZ 85013
direct 602.406.3000
stjosephs-phx.org

Tuesday, July 10, 2012

Director, Division of Spent Fuel and Transportation
U.S. Nuclear Regulatory Commission
Office of Nuclear Material and Safeguards
Washington, DC 20555

Dear Madam or Sir:

St. Joseph's Hospital and Medical Center/The Barrow Neurological Institute operates a Perfexion Gamma Knife unit for the treatment of neurological disorders. The unit is loaded with ^{60}Co and requires a periodic reload every five years or so. Our reload had long been scheduled for August, 2012 with the Perfexion manufacturer Elekta. Recently we were informed that the U.S. NRC will no longer allow the use of the only approved Gamma Knife source shipping cask available currently in the US. The practical effect of this decision is our ^{60}Co reload will be delayed until 2013.

Our Medical Center fully supports the safety of the public and Homeland security. But the shipping cask decision will directly impact patient care in Arizona. We are the only Gamma Knife center in the State. We routinely treat the full spectrum of neurological disorders appropriate for the Gamma Knife. With our aging ^{60}Co sources current treatment times are now averaging 2.5 hours. Patients must remain perfectly still, attached to a head frame, for upwards of 2 – 3 hours. Patient tolerance and thus accuracy of treatment of brain anatomical areas becomes a concern with weak sources. About 60% of our patients have trouble tolerating the currently lengthened treatment times. This situation will only worsen if our reload is delayed until next year.

Lengthened treatment times mean fewer patients treated per day and week. This in turn creates delays in access to care. Delays in care have repercussions for those affected including decreased quality of life and decreased length of life. We estimate upwards of 150 patients will be impacted by the delay in source replacement because of the cessation of shipments of U.S. produced ^{60}Co sources for the Perfexion unit.

We respectfully request a reconsideration of the shipping cask decision.

Sincerely,

Patty White
President and CEO

David Brachman, MD
Medical Director, Radiation Oncology

Ridgeview Regional Radiation Oncology

560 South Maple Street, Suite 10 | Waconia, MN 55387

952.442.6000 | Fax: 952.442.7851 | www.mropa.com

July 13, 2012

Nuclear Regulatory Commission

To Whom It May Concern,

Patient care at the Gamma Knife Center at the University of Minnesota would be severely affected by the proposed delay in replacing the cobalt sources in our Gamma Knife. Our sources were scheduled to be replaced in December, which was already beyond the seven year point. A further delay causes the patients to endure longer treatment times, wearing the head-frame for longer periods and fewer patients can be treated if each treatment takes more time. It becomes an access to health care problem. We respectfully request your assistance to do whatever is necessary to ensure the replacement of the sources on schedule, in December 2012.

Thank you for your time and consideration of this important patient care issue.

Sincerely,



Paul W. Sperduto, MD, MPP
Co-Director, Gamma Knife Center
University of Minnesota



Minneapolis Radiation Oncology, P.A.

Business Office: 6950 France Ave S, Suite 200

Minneapolis, MN 55435 | 952.920.4915 or 1.800.920.4220

University of California
San Francisco



Radiation Oncology

Penny K. Sneed, M.D.
Professor in Residence

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San Francisco, CA 94143-0226
tel: 415/353-8900
fax: 415/353-8679
email: psneed@radonc.ucsf.edu

June 28, 2012

Nuclear Regulatory Commission

TO WHOM IT MAY CONCERN:

We are writing as co-directors of the Gamma Knife program at the University of California San Francisco in support of an extension request for continued use of the source cask used to transport Cobalt-60 sources from the supplier to Gamma Knife sites for source reloading. Our Perfexion Gamma Knife has been in use since November 2007 and is currently scheduled for source reloading in October 2012. The project is scheduled to begin October 6, 2012 and a lot of planning has already gone into this. As our Cobalt sources are close to their half-life, patient treatment times have become nearly twice as long, resulting in more patient discomfort and decreased ability to treat multiple patients per day, resulting in delayed treatment and risk of compromising patient care. It is highly important to patient comfort and quality, timely care to proceed with the source change as planned in October 2012.

Sincerely,

Penny K. Sneed, MD, FACR
Professor and Gamma Knife Program Co-Director
Department of Radiation Oncology
University of California, San Francisco

Michael W. McDermott, MD
Professor and Gamma Knife Program Co-Director
Department of Neurological Surgery
University of California, San Francisco