U. S. Nuclear Regulatory Commission ATTN: Document Control Desk Washington, DC 20555

10 February 1994

Amersham Corporation 40 North Avenue Burlington, MA 01803 54 (617) 272-2000

tel (800) 225-1383

Reply to a Notice of Violation

Mmersham QSA

Docket number: 030-29300; 030-32596; 040-08917

Amersham Corporation responds to the Notice of Violation concerning docket number 030-29300 as given below. The responses are given in the same order as requested in the Notice of Violation.

- (1) Amersham exceeded its possession limits for sealed sources on three occassions due to shipments of bulk material not arriving on the preplanned schedule. The iridium does not always arrive in accordance with the preplanned schedule due to several reasons that are difficult to control:
 - The reactor cycles of the suppliers that provide us with the bulk iridium, are constantly changing and a shipment is often shipped earlier or later than originally planned. This then overlaps with shipments coming in from other suppliers.
 - -The length of time that each shipment takes to be cleared from customs (for the import shipments) is also variable. This makes the arrival date of all of the import shipments difficult to control, again causing arrival of separate shipments to overlap.
- (2) In each case that we determined we had exceeded the possession limits for sealed sources, we immediatly took the action to convert the sealed (special form sources) into unsealed Ir-192. This brought our possession limits for both sealed and unsealed to be within our licensed possession limits.

We have also performed a more accurate assessment of existing quantities of sealed sources and better determined our permanent

inventory. This allows for better control of inventory, as we know the maximum quantity that can be initially ordered and scheduled to arrive without exceeding our possession limits.

These actions have brought us into control with keeping quantities under the possession limits under current conditions. However due to an anticipated increase in production and an increase in the spent sealed source inventory due to the low level waste issue we need to increase our possession limits for long term compliance.

- (3) To prevent any further violations, we have requested an amendment to our radioactive materials license to increase our possession limits for both sealed and unsealed sources of Ir-192. This amendment request was sent to Region I on 25 January 1994. A copy of this letter is enclosed.
- (4) We have been in compliance since September 1993, and we will be able to assure continued compliance upon receipt of the license amendment for an increase in possession limits.

I trust this contains the information necessary to close out this notice of violation. Please contact me if you require any additional information.

Sincerely,

Cathleen Roughan

Regulatory Affairs Manager

Cotaller Myles

cc: Regional Administrator

U. S. Nuclear Regulatory Commission

Region I

475 Allendale Road

King of Prussia, PA 19406

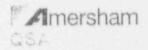


Mr. John McGrath Nuclear Material Safety Branch U. S. Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406

25 January 1994

Amersham Corporation 40 North Avenue Burlington, MA 01803 tel (617) 222-2000

tel (617) 272-2000 tel (800) 235-1383



Dear Mr. McGrath

We request an amendment to our radioactive materials license number 20-12836-01 to increase our possession limits as given below.

6. Byproduct, source and/or special nuclear material

Chemical and/or physical form 8. Maximum amount that licensee may possess at any one time under this license

F. Iridium-192

sealed sources or special form

150,000 curies

G. Iridium-192

solid metal

100,000 curies

We require this increase due to long term storage of sources returned to us for ultimate disposal from customers and to an anticipated increase in production of iridium sealed sources by approximately 60 per cent due to operational changes at the international level.

In addition we have recently made more accurate assessments of the permanent inventory, and this has shown that the permanent inventory has been slowly increasing over the last two years which takes away from the available inventory for manufacturing sealed sources. To assure that we do not exceed possession limits when there are unexpected changes in the supplier reactor cycles, we need to be able to possess greater quantities.

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We have reviewed these possession limits against the financial assurance requirements in 10 CFR 30.35 and the emergeny plan requirements in 10 CFR 30.32(h) and based on the following information have determined that there are no changes required to our existing program to comply with these.

10 CFR 30.35(a) and 30.35(b) only apply to unsealed and sealed sources with a half life of greater than 120 days, Iridium-192 has a half life of 74 days.

Amersham has received an exemption from the requirement to have an emergency plan based on the condition that we limit the amount of unsealed Iridium-192 in the hot cells to 6000 curies. This requirement is listed as condition 15 on our current license. Although we are increasing the amount of unsealed Iridium-192 we can possess, we will not have more than 6000 curies open at any one time in the hot cells. The additional unsealed Iridium-192 will be stored in screw top capsules which are secured in shielded storage containers as described in our original request for an exemption from the emergency plan requirements.

I have enclosed the applicable amendment fee in accordance with 10 CFR 170 of \$460 to process this request. If you have any questions concerning this request or would like additional information, please contact me at extension *210.

Sincerely,

Cathleen Roughan

Regulatory Affairs Manager