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Rosenblum, Goldenhersh, Silverstein  
& Zafft, P.C.  
ATTN: Richard E. Greenberg, Esq.  
7777 Bonhomme Avenue  
Fourteenth Floor  
St. Louis, MO 63105

EA 89-257

Gentlemen:

Reference: Letter Dated January 26, 1990, and Enclosed Petition for Limited Modification of Order Suspending Licenses Pending Hearing and Review of Order

We are in receipt of your letter on behalf of American Radiolabeled Chemicals, Inc. (ARC), dated January 26, 1990, with the enclosed Petition For Limited Modification Of Order Suspending Licenses Pending Hearing And Review Of Order (Petition). Specifically, you requested limited modification of the Order to permit shipping of regulated products from ARC's current inventory and receipt and transfer of prepackaged materials from other licensed vendors. We have completed our initial review of the Petition, and believe that several matters require clarification or amplification before reaching a decision on your request. Although we do not necessarily agree with all of the bases set forth in the Petition, we do not feel that it is necessary, at this time, to resolve those issues.

The following additional information is requested:

1. The Petition specifically requests in Section A that the Order be amended to permit ARC to sell and ship regulated products from its current stock or inventory and that it be permitted to purchase prepackaged materials from other licensed vendors for reshipment to customers. Although it is not specifically stated, we understand your request to mean that no work would be performed which would involve the actual handling of radioactive materials or radiolabeled chemicals themselves, but rather that all such material would be and will remain in sealed containers during the requested operation. Please verify that our understanding is correct.
2. The Petition states in Section A.2, "All shipments to be supervised by an independent consultant, licensed and trained in health physics." Please provide us with the name and qualifications of the individual who will supervise the shipping activities. We would plan to review and approve this individual prior to authorization of the requested activity.

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3. Please identify the individual who will act as Radiation Safety Officer (RSO) for the requested activities and provide this individual's qualifications for Region III approval. This individual shall not be Surendra or Karen Gupta.
4. Please verify that the independent consultant who is to supervise the shipping and repackaging will be present and in direct supervision of personnel at all times when personnel are preparing and shipping licensed material.
5. Please verify that the independent consultant will be adequately trained in the requirements of the ARC NRC license and that personnel conducting shipping and repackaging tasks will be properly trained in accordance with 10 CFR Part 19 and ARC's NRC license to conduct those tasks.
6. The individual who supervises the shipping activities, including the related package labeling and documentation preparation, must have complete independence from the current company management in making decisions in this area. Please verify that the President or Vice President will not direct or supervise these activities and describe any agreements that will assure such independence.
7. Please describe using an annotated floor plan and supporting text the physical location where shipments will be prepared. In addition, please describe your plans for monitoring and, if necessary, decontamination to levels in your current license of all areas that will be used to receive, repackage, and ship licensed materials including the areas where any equipment utilized in this process is located and where material will be or is being stored. Describe these areas in terms of a floor plan. Also, please describe the contamination control procedures that will be employed for ensuring that these areas do not become recontaminated.
8. Please verify that: (a) all packages prepared for shipment will be wipe tested for external radioactive contamination prior to shipment; (b) records of these tests will be maintained for Commission review; and (c) properly completed labels and shipping papers will be affixed to packages and accompany all shipments, respectively. In addition, please provide, for Commission review, the written procedures or instructions which will be utilized in conducting the tasks addressed above as well as in assuring the specified conditions in Section A of the Petition.
9. Please describe what equipment will be used for the analysis of the package wipe tests and area contamination surveys. In addition, please

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provide certification from your independent health physics consultant that the equipment is functioning properly and calibrated, and submit quality control procedures that will be utilized to ensure proper continued operation of this equipment.

- 10. Please verify that all activities described above will be conducted in accordance with all applicable ARC license conditions and Nuclear Regulatory Commission and Department of Transportation regulations.

If you have any questions regarding this letter, please contact Bruce Berson, Regional Counsel, at (708) 790-5732.

Sincerely,

A. Bert Davis  
Regional Administrator

bcc w/ltr dtd 01/26/90:  
ARC License File  
No. 24-21362-01  
J. Clifford, OEDO  
J. Lieberman, OE  
J. Golberg, OGC  
R. Bernero, NMSS

RIII GLS 2/5/90	RIII Caniano 2/5/90	RIII Mallett 2/5/90	RIII Berson 2/5/90	RIII Grobe 2/2/90	RIII Noretus 2/5/90	RIII Poperiello 2/5/90	RIII Davis 2/5/90
NMSS per telecon w/ J. Clifford Glenn 02/2/90	OGC per telecon w/ J. Clifford Lewis 2/2/90	OE per telecon w/ Ed Berson Lieberman 2/5/90					