

September 26, 1996

Mr. Gyo Shinozaki  
Hochiki America Corporation  
15412 Electronic Lane, #210  
Huntington Beach, CA 92649

Dear Mr. Shinozaki:

This letter is in response to your fax dated September 19, 1996 concerning your inspection procedures in your revised quality assurance/control (QA/QC) program. In your QA/QC program, it was stated that a written certification will accompany each shipment from Hochiki Japan verifying that inspections for design conformance and removable contamination have been done. However, you have not provided adequate assurance that the manufacturer's QA/QC program and procedures are adequate to ensure that the inspections performed are in accordance with the commitments contained in your application for the inspections, as well as the written certification indicating results of these inspections. The assurance could be provided through periodic checks (i.e. annual audits by Hochiki America) of the manufacturer's QA/QC program and inspection procedures. Alternatively, inspections for design conformance and removable contamination may be performed by Hochiki America as indicated in Regulatory Guide 6.9, or by any equivalent process that would provide the necessary assurance. Please provide additional information concerning your QA/QC program that provides adequate assurance that commitments made in your application will be met, that written certifications from the manufacturer contain the results of inspections performed, that only lots that have been shown to meet the inspection criteria will be distributed.

Please provide this information as soon as possible. If I can provide further clarification, please contact me at (301) 415-5787 or Douglas Broadus at (301) 415-5847.

Sincerely,



Christopher L. Brown, General Engineer  
Sealed Source Safety Section  
Medical, Academic, & Commercial  
Use Safety Branch  
Division of Industrial and  
Medical Nuclear Safety, NMSS

Distribution:

SSSS r/f  
SSD File # NR-0355-D-105-E

SSD-96-49

NE01

10

DOCUMENT NAME: C:\OFFICE\WPWIN\WPDOCS\HOCHIK2.DEF

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	IMAB	<input checked="" type="checkbox"/> IMAB	<input checked="" type="checkbox"/>					
NAME	CBrown	DBroadus						
DATE	09/24/96	09/24/96						

OFFICIAL RECORD COPY

9609300213 960926  
PDR RC \*  
SSD PDR