

REVIEWER NOTE FOR NR-0668-D-101-E

FROM: Seung J. Lee /RA/

07/18/2002

1. The **checklist** was not used because the distributor stated in the letter dated 03/23/2002 that the end product does not change, and the design and construction of both 7051 and 7052 models is the same. Therefore, no safety evaluation was performed. However, the request for additional information No. 1 (04/18/2002) was issued to clarify the QA/QC procedures in US and Japan.
2. In its response, the distributor stated that each lot received from Japanese manufacturer is accompanied by **quality control** conformance documentation, and the distributor performs their own quality conformance test procedures prior to distribution of these detectors in the US. The QA/QC procedures stated in the letter dated November 27, 1991, were reviewed and found acceptable. Both US distributor and Japanese manufacturer are ISO 9001:1994 certified (numbers are A8303 [valid until 08/20/2003] and 073 Issue 6 [valid until 01/08/2004], respectively) and there were no incident reports on these detector since the first introduction. Therefore, the US distributor's audit to Japanese manufacturer could be eliminated.