

November 21, 2013

MEMORANDUM TO: SSD Case File 13-29

Bruker Chemicals and Applied Markets
New Sealed Source and Device Registration

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SUBJECT: SAFETY EVALUATION PERFORMED FOR ECD AS AN
EXEMPT PRODUCT

Bruker Daltonics Inc. in letter dated July 29, 2013, applied for Sealed Source and Device Registration as an exempt device, in their Electron Capture Detector (ECD). Section 4.3 of NUREG-1717 guidance specifies the upper limits of activity for exempt. Specifically, ECD's may contain for distribution as exempt devices H-3 sources containing no more than 300mCi or Ni-63 sources containing no more than 20mCi.

After reviewing the Bruker's application, and in accordance with Section 4.3 of NUREG-1717 guidance, staff determined the ECD Safety Evaluation can be performed as an exempt device since the Bruker ECD contains 15mCi of Ni-63, less than the quantity stipulated in NUREG-1717.

In addition, Bruker conducted further analysis for exempt products in accordance with the methodology in Appendix A, NUREG-1717 (see the section entitled "Accident and Operational Dose Calculations for Bruker Detection Corporation ECDs"). The results of the analysis demonstrate that the ECDs are within the guidelines for exempt products.