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J. Lubinski  
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To Whom It May Concern:

Subject: **Comments re: Regulatory Guide DG-6002  
Establishing Quality Assurance Programs for the Manufacture and Distribution  
of Sealed Sources and Devices Containing Byproduct Material**

Regarding the subject matter, Nordion International Inc., 447 March Road, Kanata, Ontario, K2K 1X8, Canada, has the following comments and has recommended, as indicated, possible wording changes:

P.10 - Top of Page:

We disagree with this paragraph. It is our opinion that the Regulatory Agency should be informed prior to implementation of any significant design change that could effect the safety or efficacy of the sealed source. In this way, minor or insignificant changes which will, for example, improve production efficiency, need not be reported and/or approved by the Regulatory Agency.

P.10 - Item 4.2 to read as follows:

Once a document is revised, approved and effective, the applicant should ensure that all known copies of the document are pulled from production or ensure that the documents are not being used for production.

P.11 - Item 5 Material and Service Procurement

Third paragraph - delete the word "inspection" or "inspections" and replace with "verification".

P.12 - Item 5.2 to read as follows:

For each supplier the level of receipt verification should be based on past performance and the results of audits of the suppliers operations. Receipt verification may range from inspection of 100 percent of the materials or services received from new nonaudited suppliers to review of vendor supplied inspection and test data for the materials or services received from audited suppliers with good past performance. The level of verification should be increased etc.

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P.16 - Item 8.3 to read as follows:

In-process inspection of some materials may be performed by sampling. The level of inspection of critical materials should be commensurate with the criticality of the component and be specifically identified in a written approved plan.

P.16 - Item 8.6 to read as follows:


Inspection of production processes should follow a checklist that lists the acceptance criteria. Some inspections may be performed by qualified production staff instead of the QC Department etc.

P.21 - Item 12.2 to read as follows:

The completed audit checklist or equivalent mechanism (such as a corrective action request) should include etc.

Thank-you for your attention to this matter and please feel free to call should you have any questions.

Sincerely,



P.A. Gray, Manager  
Safety, Environment & Regulatory Affairs

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