

February 3, 2010

MEMORANDUM TO: R. W. Borchardt  
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS – SECY-09-0035 – PROPOSED RULE:  
REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT  
MATERIAL, PARTS 30, 31, 32, 40, AND 70 (RIN 3150-AH91)

The Commission has approved the staff's recommendation to publish the proposed amendments to 10 CFR Parts 30, 31, 32, 40, and 70 in the *Federal Register*, subject to the modifications noted below.

The staff should consider whether the clarity of the Federal Register Notice would be enhanced by the addition of a section containing "Questions and Answers," similar to sections that have been included in Federal Register Notices for other rulemakings.

The notice should include a section that summarizes all the requests for comments contained in the notice to ensure readers can comprehensively understand the issues at hand and can then make informed comments.

The justification for the proposed new class exemption for certain types of industrial devices should be based only on safety considerations. The discussion on pages 22 and 23 should be revised to reflect that the difficulty of maintaining accountability of these types of devices is not the basis for the proposed revision.

The proposed new class exemption for certain types of industrial devices should be highlighted for public comment.

The proposal to remove unnecessary limitations from the class exemption for gas and aerosol detectors by revising the requirement of "designed to protect life or property from fires and airborne hazards" to instead be "designed to protect health, safety, or property," should be highlighted for public comment.

The proposal to raise the NRC's statistical acceptance criteria; i.e., increasing the required confidence that the Tolerance Percent Defective will not be exceeded from the current 90 percent to 95 percent, should be highlighted for public comment.

The proposal to require that distribution of any part, or sub-lot, of a rejected lot must be in accordance with procedures spelled out in the license and that testing after repairs must be performed by an independent reviewer should be highlighted for public comment.

The notice should be revised to include a table that clearly indicates the Agreement State compatibility requirements for each proposed regulation change.

The staff should remove the speculative references to prospective Commission action to expand the National Source Tracking System that appear on page 27 and may appear elsewhere.

To more clearly explain how new regulatory requirements will be implemented on a case-by-case basis during amendment or renewal of a specific license authorizing distribution, the staff should augment the notice with a discussion that clarifies the specific changes being contemplated to quality control, quality assurance and prototype testing requirements.

Rather than address the safety criteria discussed in this proposal during this rulemaking, the staff shall consider them as part of its effort to develop the technical basis for possible revision of the NRC's radiation protection regulations to be consistent with the 2007 Recommendations of the International Commission on Radiological Protection (ICRP-103). The staff and the Advisory Committee on Reactor Safeguards have indicated that the current regulatory framework for radiation protection continues to provide for adequate protection of worker and public health and safety and of the environment, and no new information has been provided to support changing the safety criteria at this time.

Many of the criteria contained in the Commission's 1965 Consumer Product Policy Statement are still valid for approval of products intended for use by the general public. However, some of this information is dated, so the staff should update this policy statement concurrent with this rulemaking.

The staff should ensure that it has completed revising the licensing and inspection guidance, as appropriate, affected by this rulemaking by the time the draft final rule is provided to the Commission for consideration. Should the Commission direct that the final rule be issued, the staff should publish the revised guidance for public comment as soon thereafter as possible.

cc: Chairman Jaczko  
Commissioner Klein  
Commissioner Svinicki  
OGC  
CFO  
OCA  
OPA  
Office Directors, Regions, ACRS, ASLBP (via E-Mail)  
PDR