



DOE Packaging Certification Program

DOE Quality Assurance Program Approval Guidance on Recent Changes to 10 CFR Part 71 and DOE Order 460.1D

In recent years, the Nuclear Regulatory Commission (NRC) has relaxed the regulations of 10 CFR Part 71 regarding two requirements for Subpart H Quality Assurance Programs (QAP) approved by NRC. This guidance document issued by the DOE Packaging Certification Program (PCP) addresses these changes and their applicability to DOE elements in lieu of the recently revised DOE Order 460.1D, *Hazardous Materials Packaging and Transportation Safety*, approved 12-20-2016. This guidance document only applies to DOE elements and persons under contract to DOE elements.

QAP Renewal Period Changes from 5 years to 10 years

In 2004, the NRC changed the renewal period for QAP approvals issued under 10 CFR Part 71 from 5 years to 10 years in order to reduce the unnecessary regulatory burden of some administrative actions. This change was announced in *NRC Regulatory Information Summary (RIS) 2004-18, Expiration Date for 10 CFR Part 71 Quality Assurance Program Approvals*, dated December 1, 2004 (https://rampac.energy.gov/docs/default-source/nrcinfo/ris_200418.pdf).

The regulation §71.38, *Renewal of a certificate of compliance or quality assurance program approval*, does not specify a QAP duration, but states, "...Quality Assurance Program Approval expires at the end of the day, in the month and year stated in the approval." The expiration date is listed on the form issued by NRC when they approve a QAP: NRC Form 311, *Quality Assurance Program Approval for Radioactive Material Packages*.

DOE did not adopt this change. Order 460.1C or 460.1D; Order 460.1D, Section 4.a.(3)(d) still requires a renewal period of 5 years.

QAP Expiration and Changes (Revisions) to QAP

In 2015, the NRC amended §71.38 to remove QAP approval renewal from that regulation altogether, and removed the expiration date block from Form 311. There are no longer expiration dates for NRC QAP approvals; consequently, NRC issued new Form 311s, without an expiration date block, to all their current QAP approval holders by September 2015.

DOE did not adopt this change. Order 460.1D, Section 4.a.(3)(d) still requires a renewal period of 5 years.

Changes (revisions) to a previously approved NRC QAP are addressed in the newly added regulation, §71.106, *Changes to quality assurance program*. The significant change under §71.106 is NRC will now allow some changes to be made to QAPs previously approved under 10 CFR Part 71, without obtaining additional NRC approval. This change is consistent with the



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process that the NRC has used to approve changes that are made to the QAP descriptions for nuclear power plants licensed under 10 CFR Part 50 through the provisions at §50.54(a). The NRC now allows QAP changes to be implemented without their prior approval if the “change does not reduce the commitments in the quality assurance program previously approved by the NRC.” Examples of changes that are not considered reductions in commitment are provided in §§71.106(b)(1) through (5).

DOE did not adopt this change. However, Order 460.1D, Section 4.a.(3)(d) states “Any revision, except spelling corrections and non-substantive changes to punctuation or editorial items, to a QA program approved by the DOE CO ... must be submitted to the DOE CO..., for approval.”

Under §71.106(b), in cases where the QAP holder made changes that did not reduce commitments, the QAP holder must submit their QAP to NRC every 24 months, from the date the Form 311 was signed. If no changes were made during the 24 month reporting period, the submittal is still required and would indicate no changes were made.

DOE did not adopt this change, but strongly recommends DOE elements and persons under contract to DOE elements to submit an information-only copy of any QAP revision for “spelling corrections and non-substantive changes to punctuation or editorial items” to PCP for situational awareness.

If you have any questions, please contact me at or Dr. James M. Shuler of my staff, at (301) 903 5513.

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