

Comments on NRC IP 71111 21N.03, Commercial –Grade Dedication

The EPRI logo is rendered in a white, stylized, blocky font. The letters 'E', 'P', 'R', and 'I' are interconnected, with the 'P' and 'R' having a distinctive shape. The logo is positioned on the left side of the slide, partially overlapping a faint blue globe background.

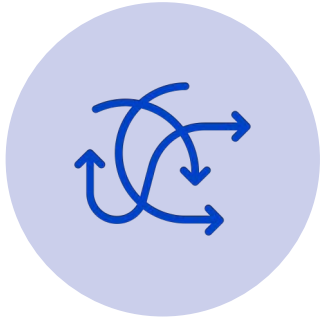
EPRI

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US Nuclear Regulatory Commission Public Meeting
September 20, 2022

Current NRC and industry CGD guidance, and terminology is not recognized



Potential to undo common industry understanding of CGD achieved subsequent to NRC Office of Inspector General Report OIG-11-A-08



In some cases, language reflects pre-1996 (1979) version of 10CFR21 (“designation” versus “acceptance”)



Final Regulatory Basis to Clarify 10 CFR PART 21, “Reporting of Defects and Noncompliance” (August 2015, [ML15152A457](#))



The phrase “designed and manufactured” means “controlled”

ML22234A207 – Comments 1, 3, 22, 23, 25, 26, 27, 28, 29

Scope is expansive and includes areas that are not part of the commercial-grade dedication process



Inspection criteria for these areas is not included in the IP
Non-CGD activities should not be inspected to CGD criteria



Procurement from 10CFR50, Appendix B-compliant suppliers



10CFR50.69 procurements and alternate treatments



Design and establishing suitability of design (equipment qualification)

ML22234A207 – Comments 2, 4, 5, 6, 17, 18, 19, 20, 24

Assumption that vendor technical data and information about original manufacturing processes is available for all commercial grade items



Some commercial-grade suppliers consider their technical data to be proprietary



10CFR50, Appendix B does not include a requirement to document supplier manufacturing processes



EPRI and licensees developed the commercial-grade dedication process to to accept commercial-grade items when original manufacturer/supplier design and acceptance criteria is not available

ML22234A207 – Comments 7, 8, 11, 13

Assertion that establishing suitability of design is a CGD activity



Establishing suitability of design occurs before acceptance

Design is addressed in 10CFR50, Appendix B, **Criterion III** - Design Control



Commercial-grade dedication is defined in 10CFR21 as an acceptance process

Acceptance is addressed in 10CFR50, Appendix B, **Criterion VII** - Control of Purchased Material, Equipment, and Services

ML22234A207 – Comments 9, 10

Assertion that a dedicating entity can impose controls on commercial-grade item's sub-tier suppliers

Controls on sub-tier suppliers are not necessary for effective dedication

Commercial-grade items can not always be purchased directly from a manufacturer

Commercial suppliers are typically not receptive to additional requirements

Commercial suppliers are typically not willing to provide information about sub-tier suppliers

ML22234A207 – Comment 16

EPRI Comments (ML22234A207) associated with each category

Category	Comment
Not recognizing current NRC and industry CGD guidance and terminology – in some cases going back to language used prior to Part 21 revisions	1, 3, 22, 23, 25, 26, 27, 28, 29
<p>Scope is expansive and includes activities that are not part of commercial-grade dedication and in some cases activities to which 10CFR21 does not apply.</p> <ul style="list-style-type: none"> • Potential to result in confusion on what CGD is and is not • Potential for non-CGD activities to be incorrectly evaluated based on CGD criteria (the only criteria included in the IP) • 10CFR50.69 and Appendix B procurements • Establishing suitability of design, including equipment qualification 	2, 4, 5, 6, 17, 18, 19, 20, 24
Assumption that vendor technical data and information about original manufacturing processes is available for all commercial grade items	7, 8, 11, 13
Suggestion that establishing suitability of design is a CGD activity	9, 10
Assumption that a dedicating entity can impose controls on sub-tier suppliers to commercial-grade item suppliers/manufacturers	16
Administrative	12, 14, 15, 17, 21



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