

An Introduction to NRC Documents

June 2022

NUPIC Vendor Conference
Detroit, MI.



Greg Galletti

Quality Assurance and Vendor Inspection Branch, Office of Nuclear Reactor Regulation



TOPICS

- Regulations
- Generic Communications
- Licensing Reviews
- Inspection-related Documents
- Enforcement
- Q&A



NRC DOCUMENTS

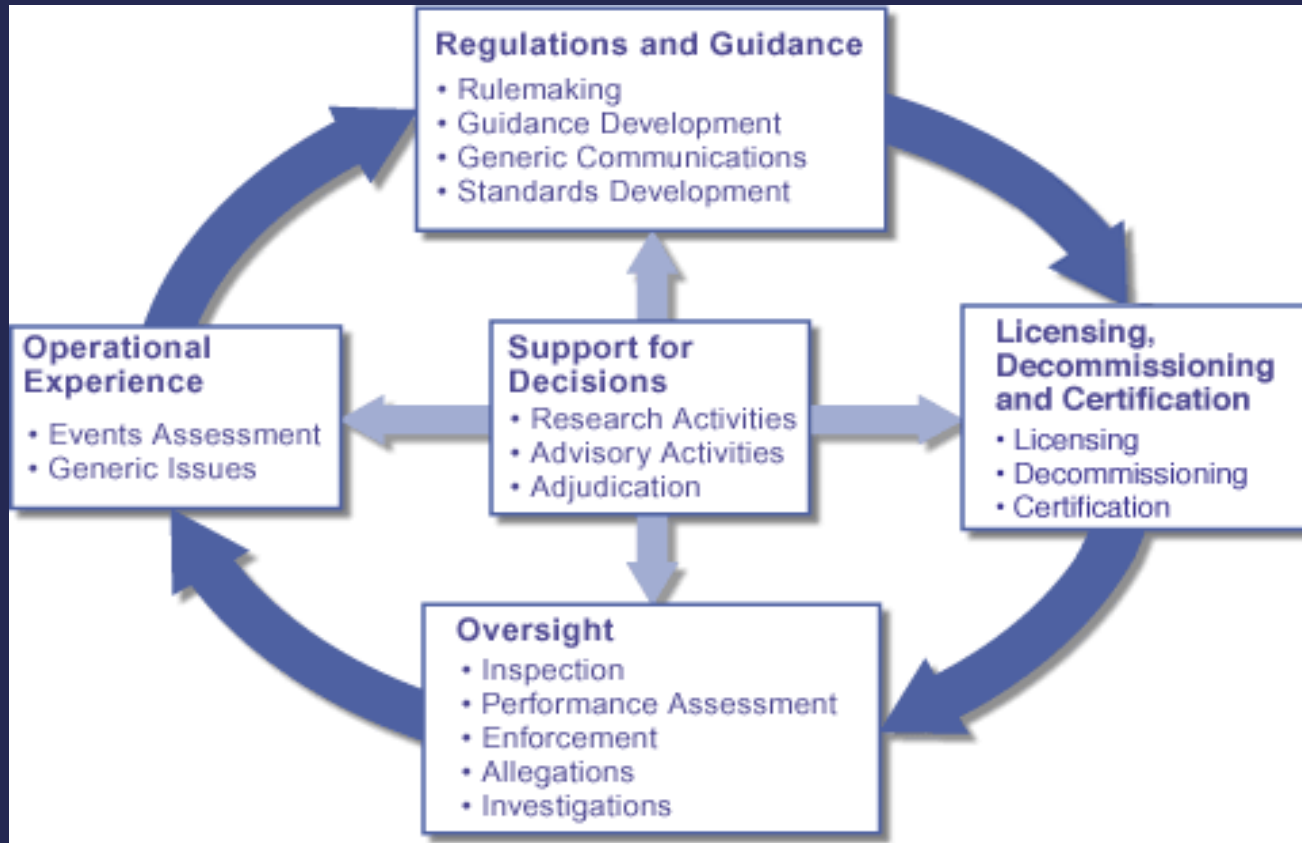


Figure 1. How the NRC Regulates



REGULATIONS

Requirements binding on all persons and organizations who receive a license from NRC to use nuclear materials or operate nuclear facilities

10 CFR 50.34 – Contents of Applications; Technical Information

10 CFR Part 52 – Licenses, certifications, and approvals for nuclear power plants

10 CFR 50.54 - Conditions of licenses

10 CFR Part 50 Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

10 CFR Part 21 Reporting of defects and noncompliance



REGULATORY GUIDES (RG)

The Regulatory Guide series provides guidance to licensees and applicants on implementing specific parts of the NRC's regulations, techniques used by the NRC staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits or licenses

RG 1.28, "Quality Assurance Program Criteria (Design and Construction)"

RG 1.33, "Quality Assurance Program Requirements (Operation)"

RG 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21"

RG 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants"

RG 1.231, "Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants"

RG 1.26, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants"



GENERIC LETTERS (GL)

Transmittals to request an action, circulate technical or policy positions, or solicit participation in voluntary programs. Generic letters (1) request licensee actions and/or information to address issues regarding emergent or routine matters of safety, security, safeguards, or environmental significance, and (2) require a written response.

GL 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products"

GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs"

GL 93-02, "NRC Public Workshop on Commercial Grade Procurement and Dedication"



INFORMATION NOTICES (IN)

Information notices communicate operating or analytical experience to the nuclear industry. Information notices may also communicate the results of recently completed research. The industry is expected to review the information for applicability and consider appropriate actions to avoid similar problems.

Vendor Inspection Related NRC Information Notices (IN) Issued Since 2010

IN 2011-01: **Commercial-Grade Dedication** Issues Identified During NRC Inspections

IN 2014-11: Recent Issues Related to the Qualification and **Commercial-Grade Dedication** of Safety-Related Components

IN 2015-12: Unaccounted for Error Terms Associated With the Irradiation Testing and Environmental Qualification of Important-To-Safety Components

IN 2016-01: Recent Issues Related to the **Commercial Grade Dedication** of Allen Bradley 700-Rtc Relays

IN 2016-09: Recent Issues Identified When Using Reverse Engineering Techniques in the Procurement of Safety-Related Components

IN 2017-05: Potential Binding of Schneider Electric/Square-D Masterpact NT And NW 480-Vac Circuit Breaker Anti-Pump Feature

IN 2018-11: Kobe Steel Quality Assurance **Record Falsification**



SECY - COMMISSION PAPERS

Written issue papers the NRC staff submits to the Commission to inform them about policy, rulemaking, and adjudicatory matters.

SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards"

The staff of the U.S. Nuclear Regulatory Commission (NRC) performed a review of international QA standards (ISO 9001-2000) against the existing framework of Appendix B to 10 CFR Part 50, and assessed approaches for adopting international quality standards for safety-related components in nuclear power plants into the existing regulatory framework.



REGULATORY INFORMATION SUMMARIES (RIS)

RIS' are used to (1) communicate and clarify NRC technical or policy positions on regulatory matters that have not been communicated to or are not broadly understood by the nuclear industry, (2) inform the nuclear industry of opportunities for regulatory relief, (3) communicate previous NRC endorsement of industry guidance on technical or regulatory matters, (4) provide guidance to applicants and licensees on the scope and detail of information that should be provided in licensing applications to facilitate NRC review, and (5) request the voluntary participation of the nuclear industry in NRC-sponsored pilot programs or the voluntary submittal of information which will assist the NRC in the performance of its functions.

RIS 2018-05: ***Supplier Oversight*** Issues Identified During Recent NRC Vendor Inspections

RIS 2016-01: Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services

RIS 2015-08: Oversight Of ***Counterfeit, Fraudulent, And Suspect Items*** in the Nuclear Industry



BULLETINS (BL) AND CIRCULARS (CR)

Bulletins (1) request licensee actions and/or information to address significant issues regarding matters of safety, security, safeguards, or environmental significance that have great urgency, and (2) require a written response.

BL 79-01, "Environmental Qualification of Class IE Equipment"
BL 79-05, "Nuclear Incident at Three Mile Island" BL 95-01: Quality Assurance
Program For Transportation of Radioactive Material
BL 2007-01, "Security Officer Attentiveness"

Circulars transmit information to licensees or permit holders when (1) the information is of safety, safeguards, or environmental interest, (2) the NRC wishes to disseminate the information within 30 days, and (3) no reply is necessary in order for NRC to assess the significance of the matter.

CR 77-01, "Malfunctions of Limiting Valve Operators Description of
Circumstances"
CR-78-08, "Environmental Qualification of Safety-Related Electrical Equipment at
Nuclear Power Plants"



NUREGS

Reports or brochures on regulatory decisions, results of research, results of incident investigations, and other technical and administrative information.

NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants"

NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition"

Chapter 17 – "Quality Assurance"

NUREG-0737, "Clarification of TMI Action Plan Requirements"

NUREG-1358, Supplement No.1, "Lessons Learned From the Special Inspection Program For Emergency Operating Procedures. Conducted October 1988 - September 1991"



SAFETY EVALUATION REPORTS (SER)

SERs are used to document the bases for staff approval for a variety of activities including (1) QA-related topical reports submittals by licensees, suppliers, and various applicants; (2) changes to approved or accepted QA Program Descriptions; (3) approval of license amendment requests such as changes to the plant design.

Final Safety Evaluation for Technical Report NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1

Callaway Plant, Unit No. 1 – Operating Quality Assurance
Manual Change Revision 34b (EPID L-2020-LLQ-0004 [COVID-19])

Columbia Generating Station - Reduction In Commitment To The Operational
Quality Assurance Program Description (EPID L-2020-LLQ-0003)[Covid-19]

Waterford Steam Electric Station, Unit 3 - Issuance Of Amendment No. 260
Re: Digital Upgrade To The Core Protection And Control Element Assembly
Calculator System (EPID L 2020 LLA 0164)



INSPECTION MANUAL CHAPTERS (IMC)

The IMCs provides guidance to NRC inspection staff on implementing the NRC's inspection program for licensed facilities, supplier organizations, and the various license and permit applicants.

Inspection Type	Manual Chapters	Inspection Procedures	Responsible Organization(s)
Vendor	IMC-2507 IMC-0617	IP-35710 IP-36100 IP-43002 IP-43003 IP-43004 IP-43005 IP-43006 IP-81811	QA and Vendor Inspection Technical Branches
Construction (ITAAC)	IMC-2503	IP-65001.22 IP-65001.23	



INSPECTION PROCEDURES (IP)

IPs provides guidance to NRC inspection staff for the conduct of various NRC inspections.

Inspection Procedure	Title
IP35710	QUALITY ASSURANCE INSPECTION OF SOFTWARE USED IN NUCLEAR APPLICATIONS
IP36100	INSPECTION OF 10 CFR PART 21 AND PROGRAMS FOR REPORTING DEFECTS AND NONCOMPLIANCE
IP43002	ROUTINE INSPECTIONS OF NUCLEAR VENDORS
IP43003	REACTIVE INSPECTIONS OF NUCLEAR VENDORS
IP43004	INSPECTION OF COMMERCIAL-GRADE DEDICATION PROGRAMS
IP43005	NRC OVERSIGHT OF THIRD-PARTY ORGANIZATIONS IMPLEMENTING QUALITY ASSURANCE REQUIREMENTS
IP 43006	INSPECTION OF THE IMPLEMENTATION OF MITIGATION STRATEGIES REGULATION REGARDING THE USE OF NATIONAL SAFER RESPONSE CENTERS
IP81811	PROTECTION OF SAFEGUARDS INFORMATION BY DESIGN CERTIFICATION APPLICANTS AND VENDORS
IP65001.22	INSPECTION OF DIGITAL INSTRUMENTATION AND CONTROL (DI&C) SYSTEM/SOFTWARE DESIGN ACCEPTANCE CRITERIA (DAC) – RELATED TO ITAAC
IP65001.23	INSPECTION OF HUMAN FACTORS ENGINEERING VERIFICATION AND VALIDATION ITAAC



ENFORCEMENT POLICY AND MANUAL

The Enforcement Policy and Manual provides guidance to the NRC staff. The Manual was first published in June 1990 as a tool to assist the NRC staff in implementing the Commission's enforcement program consistent with NRC's Enforcement Policy.

The Manual contains procedures, requirements, and background information used by the staff that develop or review enforcement actions.

NRC Enforcement Policy, sets forth the general principles governing the NRC's enforcement program and the Commission's expectations regarding the process to be used by the NRC to assess and disposition violations of NRC requirements.



NOTICES OF VIOLATION (NOV) AND NOTICES OF NONCONFORMANCE (NON)

NOVs – A Notice of Violation (NOV) (see 10 CFR 2.201, “Notice of Violation”) is a written notice setting forth one or more violations of a legally binding requirement and normally requires the recipient to provide a written response describing (1) the reasons for the violation or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken by the licensee or other person and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved.

NONs - Notices of Nonconformance will be used for contractors who fail to meet commitments related to NRC activities but are not in violation of specific requirements.



QUESTIONS

