March 1, 2005

Mrs. Mary G. Korsnick
Vice President R.E. Ginna Nuclear Power Plant
R.E. Ginna Nuclear Power Plant, LLC
1503 Lake Road
Ontario, NY 14519

SUBJECT: R. E. GINNA NUCLEAR POWER PLANT - ISSUANCE OF AMENDMENT RE: INCREASED FLEXIBILITY IN MODE RESTRAINTS (TAC NO. MC2310)

Dear Mrs. Korsnick:

The Commission has issued the enclosed Amendment No. 88 to Renewed Facility Operating License No. DPR-18 for the R. E. Ginna Nuclear Power Plant. This amendment is in response to your application dated March 1, 2004.

The amendment modifies Technical Specification (TS) requirements to adopt the provisions of Industry/TS Task Force (TSTF) change TSTF-359, "Increased Flexibility in Mode Restraints." The availability of TSTF-359 for adoption by licensees was published in the *Federal Register* on April 4, 2003 (68 FR 16579).

A copy of the related Safety Evaluation is also enclosed. A Notice of Issuance will be included in the Commission's biweekly *Federal Register* notice.

Sincerely,

/RA/

Donna Skay, Senior Project Manager, Section 1
Project Directorate I
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Docket No. 50-244

Enclosures: 1. Amendment No. 88 to Renewed License No. DPR-18
2. Safety Evaluation

cc w/encls: See next page

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cc w/encls: See next page

Accession Number: ML050610181

OFFICE	CLIIP LPM	PDI-1\PM	PDI-1\LA	IROB/TSS	PDI-1\SC
NAME	WReckley	DSkay	SLittle	TTjader	RLaufer
DATE	2/17/05	2/23/05	3/1/05	3/1/05	3/1/05

Official Record Copy

DATED: March 1, 2005

AMENDMENT NO. 88 TO RENEWED FACILITY OPERATING LICENSE NO. DPR-18 GINNA NUCLEAR POWER PLANT

PUBLIC
PDI-1 R/F
RLaufer
OGC
GHill (2)
TBoyce
ACRS
GMatakas, RI
DSkay
SLittle

cc: Plant Service list

R.E. GINNA NUCLEAR POWER PLANT, LLC

DOCKET NO. 50-244

R. E. GINNA NUCLEAR POWER PLANT

AMENDMENT TO RENEWED FACILITY OPERATING LICENSE

Amendment No. 88
Renewed License No. DPR-18

1. The Nuclear Regulatory Commission (the Commission or the NRC) has found that:

   A. The application for amendment filed by the R.E. Ginna Nuclear Power Plant, LLC (the licensee) dated March 1, 2004, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I;

   B. The facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission;

   C. There is reasonable assurance: (i) that the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the Commission's regulations;

   D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public; and

   E. The issuance of this amendment is in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

2. Accordingly, the license is amended by changes to the Technical Specifications as indicated in the attachment to this license amendment, and paragraph 2.C.(2) of Renewed Facility Operating License No. DPR-18 is hereby amended to read as follows:

(2) Technical Specifications

The Technical Specifications contained in Appendix A, as revised through Amendment No. 88, are hereby incorporated in the license. The licensee shall operate the facility in accordance with the Technical Specifications.

3. This license amendment is effective as of the date of its issuance and shall be implemented within 60 days.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Richard J. Laufer, Chief, Section 1
Project Directorate I
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Attachment:
Changes to the Technical
Specifications

Date of Issuance: March 1, 2005

ATTACHMENT TO LICENSE AMENDMENT NO. 88

RENEWED FACILITY OPERATING LICENSE NO. DPR-18

DOCKET NO. 50-244

Replace the following pages of the Appendix A Technical Specifications with the attached revised pages. The revised pages are identified by amendment number and contain marginal lines indicating the areas of change.

Remove	Insert
3.0-2	3.0-2
3.0-5	3.0-5
3.1.3-1	3.1.3-1
3.3.3-1	3.3.3-1
3.4.5-1	3.4.5-1
3.4.11-1	3.4.11-1
3.4.12-2	3.4.12-2
3.4.15-1	3.4.15-1
3.4.15-2	3.4.15-2
3.4.16-1	3.4.16-1
3.5.3-1	3.5.3-1
3.5.3-2	3.5.3-2
3.6.7-1	3.6.7-1
3.6.7-2	—
3.7.4-1	3.7.4-1
3.7.5-1	3.7.5-1
3.7.5-2	3.7.5-2
3.7.5-3	3.7.5-3
3.8.1-1	3.8.1-1

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

RELATED TO AMENDMENT NO. 88 TO RENEWED FACILITY

OPERATING LICENSE NO. DPR-18

R. E. GINNA NUCLEAR POWER PLANT, INC.

R. E. GINNA NUCLEAR POWER PLANT

DOCKET NO. 50-244

1.0 INTRODUCTION

By letter dated March 1, 2004, (Agencywide Documents Access and Management System accession number ML04068090), R. E. Ginna Nuclear Power Plant, Inc. (the licensee) submitted a request for changes to the R. E. Ginna Nuclear Power Plant Technical Specifications (TSs). The requested changes would modify TS requirements for mode change limitations in Limiting Condition for Operation (LCO) 3.0.4 and Surveillance Requirement (SR) 3.0.4 to adopt the provisions of Industry/TS Task Force (TSTF) change TSTF-359, "Increased Flexibility in Mode Restraints." The availability of TSTF-359 for adoption by licensees was published in the *Federal Register* on April 4, 2003 (68 FR 16579).

On July 17, 2002, the Nuclear Energy Institute (NEI) Risk Informed TS Task Force (RITSTF) submitted proposed change, TSTF-359, Revision 7, to the Standard TS (STS) (NUREGs 1430-1434) on behalf of the industry. TSTF-359, Revision 7, proposed to change the STS LCO 3.0.4 and SR 3.0.4 requirements regarding mode change limitations by risk-informing limitations on entering the mode of applicability of an LCO. The Notice of Opportunity to Comment on the model safety evaluation (SE) using the Consolidated Line Item Improvement Process with respect to this change was published in the *Federal Register* on August 2, 2002 (67 FR 50475). The Nuclear Regulatory Commission (NRC) staff prepared a model SE incorporating changes resulting from public comments. The NRC staff has since made minor editorial changes to the SE. TSTF-359, Revision 8, as modified, provides the complete approved change as discussed in the *Federal Register* notice dated April 4, 2003. The RITSTF subsequently incorporated the modifications identified in the April 4, 2003, notice into TSTF-359, Revision 9.

This proposal is one of the industry's initiatives under the risk-informed TS program. These initiatives are intended to maintain or improve safety while reducing unnecessary burden and to make TS requirements consistent with the Commission's other risk-informed regulatory requirements, in particular 50.65 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," or the maintenance rule.

The current TSs specify that a nuclear power plant cannot go to higher modes of operation[1] (i.e., move toward power operation) unless all TS systems, normally required for the higher mode, are operable. This limitation is included (with several exceptions for some plants) in LCO 3.0.4 and SR 3.0.4. LCO 3.0.4 and SR 3.0.4 in the STS currently state, in part, that when an LCO or SR is not met, "entry into a MODE or other specified condition in the Applicability shall not be made except when the associated ACTIONS to be entered permit continued operation in the MODE or other specified condition in the Applicability for an unlimited period of time." The industry believes that this requirement is unnecessarily restrictive and can unduly delay plant startup while considerable resources are being used to resolve startup issues that are risk insignificant or low risk. A maintenance activity that takes longer than planned can delay a mode change and adversely impact a utility's orderly plant startup and return to power operation. The objective of the proposed change is to provide additional operational flexibility without compromising plant safety.

The proposed changes to LCO 3.0.4 and SR 3.0.4 would allow, for systems and components, mode changes into a TS condition that has a specific required action and completion time (CT). The licensee will utilize the LCO 3.0.4 and SR 3.0.4 allowances only when they determine that there is a high likelihood that the LCO will be satisfied within the LCO CT, after the mode change. In addition, the LCO 3.0.4 and SR 3.0.4 allowances can be applied to values and parameters in specifications when explicitly stated in the TS (non-system/component TS such as: Reactor Coolant System Specific Activity). These changes are in addition to the current mode change allowance when a required action has an indefinite CT. The LCO 3.0.4 and SR 3.0.4 mode change allowances are not permitted for the systems and components (termed "higher risk") listed below in Section 3.1.2, "Identification of Risk-Important TS Systems and Components," for the modes specified. Two examples are: (1) Westinghouse plants cannot transition from Mode 5 to Mode 4 without a high-head safety injection system train operable and (2) Westinghouse plants cannot transition up into any mode with an inoperable required emergency diesel generator.

2.0 REGULATORY EVALUATION

In 10 CFR 50.36, "Technical specifications," the Commission established its regulatory requirements related to the content of TSs. Pursuant to 10 CFR 50.36, TSs are required to include items in the following five specific categories related to station operation: (1) safety limits, limiting safety system settings, and limiting control settings; (2) LCOs; (3) SRs; (4) design features; and (5) administrative controls. The rule does not specify the particular requirements to be included in a plant's TS. As stated in 10 CFR 50.36(c)(2)(i), the "Limiting conditions for operation are the lowest functional capability or performance levels of equipment required for safe operation of the facility. When a limiting condition for operation of a nuclear reactor is not met, the licensee shall shut down the reactor or follow any remedial action permitted by the technical specifications....". By convention, the LCOs and related SRs are contained in Sections 3.1 through 3.10 of the TSs. STS Section 3.0, on "LCO and SR Applicability," provides details or ground rules for complying with the LCOs and related SRs. LCO 3.0.4 and SR 3.0.4 address requirements for LCO compliance when transitioning between modes of operation.

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[1]MODE numbers decrease in the transition "up to a higher mode of operation;" power operation is MODE 1.

TSs have taken advantage of risk technology as experience and capability have increased. Since the mid-1980's, the NRC has been reviewing and granting improvements to the TS that are based, at least in part, on probabilistic risk assessment (PRA) insights. In its final policy statement on TS improvements of July 22, 1993, the Commission stated that it expects that licensees will utilize any plant-specific PRA or risk survey in preparing their TS-related submittals. In evaluating these submittals, the NRC staff applies the guidance in Regulatory Guide (RG) 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” dated July 1998 and in RG 1.177, “An Approach for Plant-Specific, Risk-Informed Decision making: Technical Specifications,” dated August 1998. The staff has appropriately adapted this guidance to assess the acceptability of upward mode changes with equipment inoperable. This review had the following objectives:

- To ensure that the plant risk does not increase unacceptably during the actual implementation of the proposed change (e.g., when the plant enters a higher mode while an LCO is not met). This risk increase is referred to as “temporary.”

- To compare and assess the risk impact of the proposed change to the acceptance guidelines of the Commission’s Safety Goal Policy Statement, as documented in RG 1.174. The risk impact, which is measured by the average yearly risk increase associated with the change, aims at minimizing the “cumulative” risk associated with the proposed change so that the plant’s average baseline risk is maintained within a minimal range.

- To assess the licensee’s ability to identify risk-significant configurations resulting from maintenance or other operational activities and take appropriate compensatory measures to avoid such configurations.

The NRC staff reviewed the reliance on 10 CFR 50.65(a)(4) for the non-higher-risk systems and components, and related guidance to assess and manage the risk of upward mode changes. The Commission has found that compliance with the industry guidance for implementation of 10 CFR 50.65(a)(4), as endorsed by RG 1.182, “Assessing and Managing Risk before Maintenance Activities at Nuclear Power Plants,” and mandated by LCO 3.0.4, SR 3.0.4, and SR 3.0.3, satisfies the configuration risk management objectives of RG 1.177 for TS surveillance interval and CT extensions. Reliance on 10 CFR 50.65(a)(4) processes that are consistent with the provisions of the NRC-endorsed industry guidance were also found adequate for managing risk of missed surveillances as described in the *Federal Register* on September 28, 2001 (66 FR 49714).

The NRC staff review also had the objective of ensuring that existing inspection programs have the necessary controls in place to allow the NRC staff to oversee the implementation of the proposed change and reliance on 10 CFR 50.65(a)(4) processes or programs. The inspection program also allows the staff to adequately assess the licensee’s performance associated with risk assessments. The review encompassed inspection procedures (IPs) (i.e., NRC IP 62709 dated December 28, 2000, “Configuration Risk Assessment and Risk Management Process,” and NRC IP 71111.13 dated January 17, 2002, “Maintenance Risk Assessments and Emergent Work Control”), the significance determination process (SDP) (i.e., draft “Maintenance Risk Assessment and Risk Management Significance Determination Process”), enforcement guidance (i.e., draft Enforcement Manual Section 8.1.11, “Actions Involving the Maintenance

Rule"), and the associated reactor oversight process (ROP).

2.1 Proposed Change to LCO 3.0.4 and SR 3.0.4

Currently, LCO 3.0.4 does not allow entrance into a higher mode (or other specified condition) in the applicability when an LCO is not met, except when the associated actions to be entered permit continued operation in that mode or condition indefinitely or a specific exception is granted. Similarly, when an LCO's surveillances have not been met within their specified frequency, entry into a higher mode (or other specified condition) is not allowed by SR 3.0.4. The current LCO 3.0.4 reads:

> When an LCO is not met, entry into a MODE or other specified condition in the Applicability shall not be made except when the associated ACTIONS to be entered permit continued operation in the MODE or other specified condition in the Applicability for an unlimited period of time. This Specification shall not prevent changes in MODES or other specified conditions in the Applicability that are required to comply with ACTIONS.
>
> Exceptions to this Specification are stated in the individual Specifications.

The revised LCO 3.0.4 will read:

> When an LCO is not met, entry into a MODE or other specified condition in the Applicability shall only be made:
>
> (a) When the associated ACTIONS to be entered permit continued operation in the MODE or other specified condition in the Applicability for an unlimited period of time;
>
> (b) After performance of a risk assessment addressing inoperable systems and components, consideration of the results, determination of the acceptability of entering the MODE or other specified condition in the Applicability, and establishment of risk management actions, if appropriate; exceptions to this Specification are stated in the individual Specifications, or
>
> (c) When an allowance is stated in the individual value, parameter, or other Specification.
>
> This Specification shall not prevent changes in MODES or other specified conditions in the Applicability that are required to comply with ACTIONS or that are part of a shutdown of the unit.

The current SR 3.0.4 reads:

> Entry into a MODE or other specified condition in the Applicability of an LCO shall not be made unless the LCO's Surveillances have been met within their specified frequency. This provision shall not prevent entry into MODES or other specified conditions in the Applicability that are required to comply with ACTIONS.

The revised SR 3.0.4 will conform to the changes to LCO 3.0.4 and read:

> Entry into a MODE or other specified condition in the Applicability of an LCO shall only be made when the LCO's Surveillances have been met within their specified Frequency, except as provided by SR 3.0.3. When an LCO is not met due to Surveillances not having been met, entry into a MODE or other specified condition in the Applicability shall only be made in accordance with LCO 3.0.4.
>
> This provision shall not prevent entry into MODES or other specified conditions in the Applicability that are required to comply with ACTIONS or that are part of a shutdown of the unit.

The proposed LCO 3.0.4(a) retains the current allowance for when the required actions allow indefinite operation. The proposed LCO 3.0.4(b) allows entering modes or other specified conditions in the applicability except when higher-risk systems and components (listed in Section 3.1.2) for the mode being entered, are inoperable. The decision for entering a higher mode or condition in the applicability of the LCO will be made by plant management after the required risk assessment has been performed and requisite risk management actions established through the program established to implement 10 CFR 50.65(a)(4). Entry into the modes or other specified conditions in the applicability of the TSs shall be for no more than the duration of the applicable required actions CT, or until the LCO is met. Current notes in individual specifications that permitted mode changes are now encompassed by LCO 3.0.4(b) and can be removed. Notes that prohibit mode changes under LCO 3.0.4(b) must be added (i.e., for higher-risk systems and components).

The proposed LCO 3.0.4(b) allowance can involve multiple components in a single LCO or in multiple LCOs; however, use of the LCO 3.0.4(b) provisions are always contingent upon completion of a 10 CFR 50.65(a)(4) based risk assessment.

The current STS LCO 3.0.4 and STS SR 3.0.4 include notes limiting the applicability of those provisions to Modes 1, 2, 3, and 4, for pressurized-water reactors (PWRs). The notes limiting the applicability of LCO 3.0.4 and SR 3.0.4 are no longer needed and are removed by TSTF-359, Revision 9. The industry owners groups' (Boiling Water Reactors Owners Group, Babcox & Wilcox Owners Group, Combustion Engineers Owners Group, and Westinghouse Owners Group (WOG)) analyses would subsequently support adding notes to various TSs, as defined by the tables of higher-risk systems, precluding entry into Modes 5 and 6 for PWRs, and Modes 4 and 5 for boiling-water reactors (BWRs). However, the addition of notes in these cases is made unnecessary by action statements that require immediate CTs, which means that entry into the Mode or other specified condition in the Applicability is not allowed and the notes would be superfluous.

LCO 3.0.4 allowances related to values and parameters of TSs are not typically addressed by LCO 3.0.4(b) risk assessments, and are, therefore, addressed by a new LCO 3.0.4(c).

LCO 3.0.4(c) refers to allowances already in the TSs and annotated in the individual Specifications. LCO 3.0.4(c) also allows for entry into the modes or other specified conditions in the applicability of a TS for no more than the duration of the applicable required actions CT or until the LCO is met or the unit is not within the applicability of the TSs.

3.0 TECHNICAL EVALUATION

During the development of the current STSs, improvements were made to LCO 3.0.4, such as clarifying its applicability with respect to plant shutdowns, cold shutdown mode, and refueling mode. In addition, during the STS development, almost all the LCOs with CTs greater than or equal to 30 days, and many LCOs with CTs greater than or equal to 7 days, were given individual LCO 3.0.4 exceptions. During some conversions to the STSs, individual plants provided acceptable justifications for other LCO 3.0.4 exceptions. All of these specific LCO 3.0.4 exceptions allow entry into a mode or other specified condition in the TS applicability while relying on the TS required actions and associated completion times. The proposed change under evaluation would provide standardization and consistency to the use and application of LCO 3.0.4, both internal to and between each of the specifications and STS NUREGs. This proposed change will also ensure consistency through the utilization of appropriate levels of risk assessment of plant configurations for application of LCO 3.0.4. However, nothing in this SE should be interpreted as encouraging upward mode transition with inoperable equipment. Good practice should dictate that such transitions should normally be initiated only when all required equipment is operable and that mode transition with inoperable equipment should be the exception rather than the rule.

The current LCO 3.0.4(a) allowances are retained in the proposal and do not represent a change in risk from the current situation. The LCO 3.0.4(b) allowances apply to systems and components, and require a risk assessment prior to use to ensure an acceptable level of safety is maintained. The LCO 3.0.4(c) allowances apply to parameters and values which have been previously approved by the NRC in a plant's specific TSs. The licensee will provide in their TS Bases a discussion and list of each NRC-approved LCO 3.0.4(c)-specific value and parameter allowance. The Bases of LCO 3.0.4 will be revised to explain the new allowances and their use. The NRC staff performed a qualitative assessment of the risk impact of the proposed change in LCO 3.0.4(b) allowances by evaluating how the licensee's implementation of the proposed risk-informed approach is expected to meet the guidance of the applicable RGs. The staff referred to the guidance provided in RG 1.174 and in RG 1.177. RG 1.177 provides the NRC staff's recommendations on using risk information to assess the impact of proposed changes to nuclear power plant TSs on the risk associated with plant operation. Although RG 1.177 does not specifically address the type of generic change in this proposal, the staff considered the approach documented in RG 1.177 in evaluating the risk information provided in support of the proposed changes in LCO 3.0.4.

The NRC staff's evaluation of how the implementation of the proposed risk-informed approach, used to justify LCO 3.0.4(b) allowances, agrees with the objectives of the guidance outlined in RG 1.177 is discussed below in Section 3.1. Oversight of the risk-informed approach associated with the LCO 3.0.4(b) allowances is discussed below in Section 3.2.

3.1 Evaluation of Risk Management

Both the temporary and cumulative risk of the proposed change are adequately limited. The

temporary risk is limited by the exclusion of higher-risk systems and components, and CT limits contained in Section 3.1.1. The cumulative risk is limited by the temporary risk limitations and by the expected low frequency of the proposed mode changes with inoperable equipment as discussed below in Section 3.1.4. Adequate NRC oversight of the licensee's ability to use the LCO 3.0.4(b) provisions under appropriate circumstances (i.e., to identify risk-significant configurations when entering a higher mode or condition in the applicability of an LCO as discussed below in Section 3.1.5) is provided by NRC inspection of the licensee's implementation of 10 CFR 50.65(a)(4) as applied to the proposed change.

3.1.1 Temporary Risk Increases

RG 1.177 proposes the incremental conditional core damage probability (ICCDP) and the incremental conditional large early release probability (ICLERP) as appropriate measures of the increase in probability of core damage and large early release, respectively, during the period of implementation of a proposed TS change. In addition, RG 1.177 stresses the need to preclude potentially high risk configurations introduced by the proposed change. The ICCDP associated with any specified plant condition, such as the condition introduced by entering a higher mode with plant equipment inoperable, is expressed by the following equation:

$$ICCDP = \Delta R\, d = (R_1 - R_o)\, d$$

where:

ΔR = the conditional risk increase, in terms of core damage frequency (CDF), caused by the specified condition

d = the duration of the specified plant condition

R_1 = the plant CDF with the specified condition permanently present

R_o = the plant CDF without the specified condition

The same expression can be used for ICLERP by substituting the measure of risk (i.e., large early release frequency (LERF) for CDF). The magnitude of the ICCDP and ICLERP values associated with plant conditions applicable to LCO 3.0.4(b) allowances can be managed by controlling the conditional risk increase, ΔR (in terms of both CDF and LERF) and the duration, d, of such conditions. The following sections discuss how the key elements of the proposed risk-informed approach, used to justify LCO 3.0.4(b) allowances, are expected to limit ΔR and d and, thus, prevent any significant temporary risk increases.

3.1.2 Identification of Risk-Important TS Systems and Components

A major element that limits the risk of the proposed mode change flexibility is the exclusion of certain systems and associated LCOs for the mode change allowance. TS allow operation in Mode 1 (power operation) with specified levels of inoperability for specified times. This provides a benchmark of currently acceptable risk against which to measure any incremental risk inherent in the proposed LCO 3.0.4(b). If a system inoperability accrues risk at a higher rate in one or more of the transition modes than it would in Mode 1, then an upward transition into that mode should not be allowed without demonstration of a high degree of experience and sophistication in risk management. However, the risk management process evaluated in Section 3.1.5 is adequate if higher-risk systems/components are excluded from the scope of LCO 3.0.4(b).

The importance of most TS systems in mitigating accidents increases as power increases. However, some TS systems are relatively more important during lower power and shutdown operations because:

- certain events are peculiar to modes of plant operation other than power operation,
- certain events are more probable at modes of plant operation other than power operation,
- some modes of plant operation have less mitigation system capability than power operation.

The risk information submitted in support of the proposed changes to LCO 3.0.4 and SR 3.0.4 includes qualitative risk assessments performed by each owners group to identify higher-risk systems and components at the various modes of operation, including transitions between modes, as the plant moves upward from the refueling mode of operation toward power operation. The owners groups' generic qualitative risk assessments are included as attachments to TSTF-359, Revision 9. Each of the owners groups' generic qualitative risk assessments discuss the technical approach used and the systems/components subsequently determined to be of higher risk significance; the systems/components not to be granted the LCO 3.0.4 allowances for the various modes are listed. The owners groups' generic qualitative risk assessments are:

- BWR owners group Risk-Informed Technical Specification Committee, “Technical Justification to Support Risk-Informed Improvements to Technical Specification Mode Restraints for BWR Plants,” General Electric Company GE-NE A13-00464 (Rev. 2).
- “B&W owners group Qualitative Risk Assessment for Increased Flexibility in MODE Restraints,” Framatome Technologies BAW-2383, October 2001.
- Combustion Engineering owners group Task 1181, “Qualitative Risk Assessment for Relaxation of Mode Entry Restraints,” CE Nuclear Power LLC, CE NPSD-1207 (Rev. 0).
- “WOG Qualitative Risk Assessment Supporting Increased Flexibility in MODE Restraints,” January 2002.

Following interactions with the NRC staff, all owners groups used the same systematic approach in their qualitative risk assessments to identify the higher-risk systems in the STSs, consisting of the following steps:

- identification of plant conditions (i.e., plant parameters and availability of key mitigation systems) associated with changes in plant operating modes while returning to power,
- identification of key activities that have the potential to impact risk and which are in progress during transitions between modes while the plant is returning to power,
- identification of applicable accident initiating events for each mode or other specified condition in the applicability, and
- identification of the higher-risk systems and components by combining the information in

the first three steps (qualitative risk assessment).

The risk assessments properly used the results and insights from previous deterministic and probabilistic studies to systematically search for plant conditions in which certain key plant components are more important in mitigating accidents than during operation at power (Mode 1). This search was systematic, taking the following factors into account for the various stages of returning the plant to power:

- the status of accident mitigation and normally operating systems,
- the status of key plant parameters such as reactor coolant system pressure,
- the key activities that are in progress during transitions between modes which have the potential to impact risk (e.g., the transfer from auxiliary to main feedwater at some PWR plants when Mode 1 is entered),
- the applicable accident initiating events for each mode of plant operation, and
- design and operational differences among plants or groups of plants.

The following systems and components were identified by the WOG as higher-risk systems and components, when the plant is entering a new mode.

WOG Plants

System	Entering Mode
Emergency Diesel Generator (EDG)	5, 4, 3, 2, 1
Auxiliary Feedwater (AFW) System (for plants depending on AFW for startup)	4, 3, 2 ,1
High-Head Safety Injection System	4
Cold Overpressure Protection System	5, 4
Residual Heat Removal System	5

If a licensee identifies a higher-risk system for only some of the modes of applicability, the TSs for that system would be modified by a note that reads, for example, "LCO 3.0.4(b) is not applicable when entering MODE 1 from MODE 2." Systems identified as higher risk for Modes 5 and 6 for PWRs, and Modes 4 and 5 for BWRs, are also excluded from transitioning up to the mode of higher risk, and as previously discussed, notes for those transitions are superfluous. In addition, mode transitions for Modes 5 and 6 for PWRs, and Modes 4 and 5 for BWRs, will be addressed by administrative controls.

In summary, the NRC staff’s review of the owners groups' qualitative risk assessments finds that they are of adequate quality to support the application (i.e., they identify the higher-risk systems and components) associated with entering higher modes of plant operation with equipment inoperable while returning to power.

The licensee for R. E. Ginna Nuclear Power Plant has adopted the TSTF-359 wording for LCO 3.0.4 and SR 3.0.4.

- LCO 3.0.4(c) has been referenced appropriately for the TSs defining limits on parameters and values (including Condition C in LCO 3.1.3, Moderator Temperature Coefficient to maintain the limitations and flexibility provided by the existing statement that LCO 3.0.4 is not applicable).

- The licensee has, consistent with the above table, added notes to the appropriate TSs to state that the revised LCO 3.0.4(b) allowing mode changes with inoperable equipment is not applicable to the identified higher-risk systems. The licensee's application of the LCO 3.0.4(b) prohibition for AFW differs somewhat from the STS application because of plant-specific design features (primarily the inclusion of standby AFW in the LCO as an additional AFW subsystem). The licensee has proposed to incorporate TSTF-359 by stating that LCO 3.0.4(b) is not applicable for Conditions C and D in the Ginna LCO 3.7.5, "Auxiliary Feedwater (AFW) System." The NRC staff finds that the licensee's proposal provides a level of assurance comparable to the generic TSTF-359 assessment that the safety function of AFW will be available during mode changes. The proposed application of TSTF-359 to the plant-specific LCO is acceptable.

3.1.3 Limited Time in TS Required Actions

Any temporary risk increase will be limited by, among other factors, duration constraints imposed by the TS CTs of the inoperable systems. For the systems and components which are not higher risk, any temporary risk increase associated with the proposed allowance will be smaller than what is considered acceptable when the same systems and components are inoperable at power. This is due to the fact that CTs associated with the majority of TS systems and components were developed for power operation and pose a smaller plant risk for action statement entries initiated or occurring at lower modes of operation as compared to power operation.

The LCO 3.0.4(b) allowance will be used only when the licensee determines that there is a high likelihood that the LCO will be satisfied following the mode change. This will minimize the likelihood of additional temporary risk increases associated with the need to exit a mode due to failure to restore the unavailable equipment within the CT. In most cases, licensees will enter into a higher mode with the intent to move up to Mode 1 (power operation). As discussed below in Section 3.2, the revised Reactor Oversight Process (ROP) monitors unplanned power changes as a performance indicator. The ROP, thus, discourages licensees from entering a mode or other specified condition in the applicability of an LCO, and moving up in power, when there is a likelihood that the mode would have to be subsequently exited due to failure to restore the unavailable equipment within the CT. Another disincentive for licensees to enter a higher mode when an LCO is not met is related to reporting requirements. 10 CFR 50.72, "Immediate notification requirements for operating nuclear power reactors," clearly states that a report is required when the initiation of a nuclear plant shutdown is required by TSs. The NRC's oversight program will provide the framework for inspectors and other staff to follow the history at a specific plant of entering higher modes while an LCO is not met, and use such information in assessing the licensee's actions and performance.

3.1.4 Cumulative Risk Increases

The cumulative risk impact of the change to allow the plant to enter a higher mode of operation with one or more safety-related components unavailable (as proposed here), is measured by

the average yearly risk increase associated with the change. In general, this cumulative risk increase is assessed in terms of both CDF and LERF (i.e., ΔCDF and ΔLERF, respectively). The increase in CDF due to the proposed change is expressed by the following equation, which integrates the risk impact from all expected specified conditions (i.e., all expected plant conditions caused by mode changes with various TS systems and components unavailable).

$\Delta CDF = \ j \ (\Delta CDF_i) = \ j \ ICCDP_i \ f_i$
where
ΔCDF_i = the CDF increase due to specified condition i
$ICCDP_i$ = the ICCDP associated with specified condition i
f_i = the average yearly frequency of occurrence of specified condition i

A similar expression can be used for ΔLERF by substituting the measure of risk (i.e., LERF for CDF). The magnitude of the ΔCDF and ΔLERF values associated with plant conditions applicable to LCO 3.0.4(b) allowances can be managed by controlling the temporary risk increases, in terms of both CDF and LERF (i.e., ICCDP and ICLERP), and the frequency (f), of each of such conditions. In addition to the points made in the previous section regarding temporary risk increases, the following points put into perspective how the key elements of the proposed risk-informed approach, used to justify an LCO 3.0.4(b) allowance, are expected to prevent significant cumulative risk increases by limiting the frequency of its use:

- The frequency of risk significant conditions will be limited by not providing the LCO 3.0.4(b) allowances to the higher risk systems and components.

- The frequency of risk significant conditions will be limited by the requirement to assess the likelihood that the LCO will be satisfied following the mode change.

- The frequency of risk significant conditions is limited by the fact that such conditions can occur only when the plant is returning to power following shutdown (i.e., during a small fraction of time per year). Data over the past 5 years indicate that the plants are averaging 2.1 startups per year.

The addition of the proposed LCO 3.0.4(b) allowances to the plant maintenance activities is not expected to change the plant's average (cumulative) risk significantly.

3.1.5 Risk Assessment and Risk Management of Mode Changes

With all safety systems and components operable, a plant can transition up in mode to power operation. With one or more system(s) or component(s) inoperable, this change permits a plant to transition up in mode to power operation if the inoperable system(s) or component(s) are not in the pre-analyzed higher risk category, a 10 CFR 50.65(a)(4)-based risk assessment is performed prior to the mode transition, and the requisite risk management actions are taken. The proposed TS Bases state, "When an LCO is not met, LCO 3.0.4 also allows entering MODES or other specified conditions in the Applicability following assessment of the risk impact and determination that the impact can be managed. The risk assessment may use quantitative, qualitative, or blended approaches, and the risk assessment will be conducted using the plant program, procedures, and criteria in place to implement 10 CFR 50.65(a)(4), which requires

that risk impacts of maintenance activities to be assessed and managed." It should be noted that the risk assessment, for the purposes of LCO 3.0.4(b), must take into account all inoperable TS equipment regardless of whether the equipment is included in the licensee's normal 10 CFR 50.65(a)(4) risk assessment scope. The risk assessments will be conducted using the procedures and guidance endorsed by RG 1.182. The results of the risk assessment shall be considered in determining the acceptability of entering the mode or other specified condition in the Applicability, and any corresponding risk management actions. A risk assessment and establishment of risk management actions, as appropriate, are required for determination of acceptable risk for entering modes or other specified conditions in the Applicability when an LCO is not met. Elements of acceptable risk assessment and risk management actions are included in Section 11 of NUMARC 93-01 "Assessment of Risk Resulting from Performance of Maintenance Activities," as endorsed by RG 1.182, which addresses general guidance for conduct of the risk assessment, gives quantitative and qualitative guidelines for establishing risk management actions, and provides example risk management actions. These risk management actions include actions to plan and conduct other activities in a manner that controls overall risk, actions to increase risk awareness by shift and management personnel, actions to reduce the duration of the conditions, actions to minimize the magnitude of risk increases (establishment of backup success paths or compensatory measures), and determination that the proposed mode change is acceptable.

The guidance references state that a licensee's risk assessment process should be sufficiently robust and comprehensive to assess risk associated with maintenance activities during power operation, low power, and shutdown conditions (all modes of operation), including changes in plant conditions. NUMARC 93-01 states that the risk assessment should include consideration of: (1) the degree of redundancy available for performance of the safety function(s) served by the out-of-service equipment; (2) the duration of the out-of-service condition; (3) component and system dependencies that are affected; (4) the risk impact of performing the maintenance during shutdown versus at power; and, (5) the impact of mode transition risk. For power operation, key plant safety functions are those that ensure the integrity of the reactor coolant pressure boundary, ensure the capability to shut down and maintain the reactor in safe shutdown condition, and ensure the capability to prevent or mitigate the consequences of accidents that could result in potentially significant offsite exposures.

While the inoperabilities permitted by the CTs of TS required actions take into consideration the safety significance and redundancy of the system or components within the scope of an LCO, the completion times generally do not address or consider concurrent system or component inoperabilities in multiple LCOs. Therefore, the performance of the 10 CFR 50.65(a)(4) risk assessment, which looks at the entire plant configuration, is essential (and required) prior to changing operational mode. The 10 CFR 50.65(a)(4)-based risk assessment will be used to confirm (or reject) the appropriateness of transitioning up in mode given the actual status of plant safety equipment.

The risk impact on the plant condition of invoking an LCO 3.0.4(b) allowance will be assessed and managed through the program established to implement 10 CFR 50.65(a)(4). This program is consistent with RG 1.177 and RG 1.174 in its approach. The implementation guidance for paragraph (a)(4) of the Maintenance Rule addresses controlling temporary risk increases resulting from maintenance activities. This guidance, consistent with guidance in RG 1.177, establishes action thresholds based on qualitative and quantitative considerations and risk management actions. Significant temporary risk increases following an LCO 3.0.4(b)

allowance are unlikely to occur unless:

- high-risk configurations are allowed (e.g., certain combinations of multiple component outages), or

- risk management of plant operation activities is inadequate.

The requirements associated with the proposed change are established to ensure that such conditions will not occur.

The thresholds of the cumulative (aggregate) risk impacts, assessed pursuant to 10 CFR 50.65(a)(4) and the associated implementation guidance, are based on the permanent change guidelines in RG 1.174. Therefore, licensees will manage the risk by exercising LCO 3.0.4 in conjunction with the risk from other concurrent plant activities to ensure that any increase, in terms of CDF and LERF, will be small and consistent with the Commission's Safety Goal Policy Statement.

3.2 Oversight

The ROP provides a means for assessing the licensee's performance in the application of the proposed mode change flexibility. The adequacy of the licensee's assessment and management of maintenance-related risk is addressed by existing inspection programs and guidance for 10 CFR 50.65(a)(4). Although the current versions of that guidance do not specifically address application of the licensee's Section 50.65(a)(4) program to support risk-informed TSs, it is expected that, in most cases, risk assessment and management associated with risk-informed TSs would be required by Section 50.65(a)(4) anyway because maintenance activities will be involved.

Adoption of the proposed change will make failure to assess and manage the risk of an upward mode change with inoperable equipment covered by TSs, prior to commencing such a mode change, a violation of TSs. Further, as explained above in general, under most foreseeable circumstances, such a change in configuration would also require a risk assessment under 10 CFR 50.65(a)(4). Inoperable systems or components will necessitate maintenance to restore them to operability, and, hence, a 10 CFR 50.65(a)(4) risk assessment would be performed prior to the performance of those maintenance actions (except for immediate plant stabilization and restoration actions if necessary). Further, before altering the plant's configuration, including plant configuration changes associated with mode changes, the licensee must update the existing Section 50.65(a)(4) risk assessment to reflect those changes.

The July 19, 1999, *Federal Register* Notice (64 FR 38553) issuing a revision to the maintenance rule along with NRC IP 71111.13 and Section 11 of NUMARC 93-01, indicate that to determine the safety impact of a change in plant conditions during maintenance, a risk assessment must be performed before changing plant conditions. The bases for the proposed TS change mandate that the risk assessment and management of upward mode changes will be conducted under the licensee's program and process for meeting 10 CFR 50.65(a)(4). Oversight of licensee performance in assessing and managing the risk of plant maintenance activities is conducted principally by inspection in accordance with ROP Baseline IP 71111.13. Supplemental IP 62709 is used to evaluate the licensee's process, when necessary.

The ROP is described in overview in NUREG-1649, Revision 3, “Reactor Oversight Process,” and in detail in the NRC Inspection Manual. IP 71111.13 provides for verification of performance of risk assessments when they are required by 10 CFR 50.65(a)(4) and in accordance with licensee procedures. The procedure also provides for verification of the adequacy of those risk assessments and verification of effective implementation of licensee-prescribed risk management actions. The rule itself requires such assessment and management of risk prior to maintenance activities, including preventive maintenance, surveillance, and testing (and promptly for emergent work) during all modes of plant operation. The guidance documents for both industry implementation of Section 50.65(a)(4) and NRC oversight of that implementation indicate that changes in plant configuration (which would include mode changes) in support of maintenance activities must be taken into account in the risk assessment and management process. Revisions to NRC inspection guidance and licensee implementation procedures will be needed to address oversight of risk assessment and management required by TSs in support of mode changes that are not already required under the circumstances by Section 50.65(a)(4). This consideration provides performance-based regulatory oversight of the use of the proposed flexibility, and a disincentive to use the flexibility without the requisite care in planning.

In addition, the NRC staff is in the process of developing detailed significance determination process (SDP) guidance for use in assessing inspection findings related to 10 CFR 50.65(a)(4). This guidance was issued in draft for comment and is anticipated to become final during 2004. The ROP considers inspection findings and performance indicators in evaluating licensee ability to operate safely. The SDP is used to determine the significance of inspection findings related to licensee assessment and management of the risk associated with performing maintenance activities under all plant operating or shutdown conditions. Unplanned reactor scrams and unplanned power changes are two of the Reactor Safety Performance Indicators that the ROP utilizes to assess licensee performance and inform the public. The ROP will provide a disincentive to entering into power operation (Mode 1) when there is a significant likelihood that the mode would have to be subsequently exited due to failure to restore the unavailable equipment within the CT.

The licensee included in its application the revised TS Bases to be implemented with the TS change. The NRC staff finds that the TS Bases Control Program is the appropriate process for updating the affected TS Bases pages and has, therefore, not included the affected Bases pages with this amendment.

3.3 Summary

The industry, through the NEI RITSTF, submitted a proposed TS change to allow entry into a higher mode of operation, or other specified condition in the TS applicability, while relying on the TS conditions, and associated required actions and CTs, provided a risk assessment is performed to confirm the acceptability of that action. The NRC approved the standard change (TSTF-359) on April 4, 2003.

Constellation submitted a proposed TS change in accordance with TSTF-359. The proposed TS revises STS LCO 3.0.4 and SR 3.0.4, and their application to the TSs. New paragraphs (a), (b), and (c) are proposed for LCO 3.0.4. The proposed LCO 3.0.4(a) retains the current allowance, permitting the mode change when the TS required actions allow indefinite operation. Proposed LCO 3.0.4(b) is the change to allow entry into a higher mode of operation, or other specified condition in the TS applicability, while relying on the TS conditions and associated required actions and CTs, provided a risk assessment is performed to confirm the acceptability of that action for the existing plant configuration. The NRC staff review found that the process proposed by industry, and verified for applicability to Ginna, for assessing and managing risk during the implementation of the proposed LCO 3.0.4(b) allowances meets Commission guidance for TS changes. Key elements of this process are listed below.

- A risk assessment shall be performed before any LCO 3.0.4(b) allowance is invoked.

- The risk impact on the plant condition of invoking an LCO 3.0.4(b) allowance will be assessed and managed through the program established to implement 10 CFR 50.65(a)(4) and the associated guidance in RG 1.182. Allowing entry into a higher mode or condition in the applicability of an LCO after an 10 CFR 50.65(a)(4) based risk assessment and appropriate risk management actions are taken for the existing plant configuration will ensure that plant safety is maintained.

- The LCO 3.0.4(b) allowance will be used only when the licensee determines that there is a high likelihood that the LCO will be satisfied within the required action's CT.

- TS systems and components which may be of higher risk during mode changes have been identified generically by each owners' group for each plant operational mode or condition. Licensees will identify such plant-specific systems and components in the individual plant TSs. The proposed LCO 3.0.4(b) allowance does not apply to these systems and components for the mode or condition in the applicability of an LCO at which they are of higher risk.

- Plants adopting LCO 3.0.4(b) will ensure that plant procedures in place to implement 10 CFR 50.65(a)(4) address the situation where entering a mode or other specified condition in the applicability is contemplated with plant equipment inoperable. Such plant procedures typically follow the guidance in NUMARC 93-01, Section 11, as revised in February 2000 and endorsed by NRC RG 1.182.

The NRC's ROP provides the framework for inspectors and other staff to oversee the implementation of 10 CFR 50.65(a)(4) requirements at a specific plant and assess the licensee's actions and performance.

The LCO 3.0.4(b) allowance does not apply to values and parameters of the TSs that have their own respective LCOs (e.g., Reactor Coolant System Specific Activity), but instead those values and parameters are addressed by LCO 3.0.4(c). The TS values and parameters for which mode transition allowances apply, will have a note that states LCO 3.0.4(c) is applicable.

The objective of the proposed change is to provide additional operational flexibility without compromising plant safety.

4.0 STATE CONSULTATION

In accordance with the Commission's regulations, the New York State official was notified of the proposed issuance of the amendment. The State official had no comments.

5.0 ENVIRONMENTAL CONSIDERATION

The amendment changes a requirement with respect to installation or use of a facility component located within the restricted area as defined in 10 CFR Part 20 and changes surveillance requirements. The NRC staff has determined that the amendment involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released offsite, and that there is no significant increase in individual or cumulative occupational radiation exposure. The Commission has previously issued a proposed finding that the amendment involves no significant hazards consideration, and there has been no public comment on such finding (69 FR 34706). Accordingly, the amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Pursuant to 10 CFR 51.22(b) no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendment.

6.0 CONCLUSION

The Commission has concluded, based on the considerations discussed above that (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public.

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