

requested comments on it. Subsequently, to implement the Interim Policy Statement, each reactor vendor owners group and the NRC staff began developing standard TSs (STs) for reactors supplied by each vendor. The Commission then published its "Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors" (58 FR 39132), dated July 22, 1993, in which it addressed comments received on the Interim Policy Statement, and incorporated experience in developing the STs. The Final Policy Statement formed the basis for a revision to 10 CFR 50.36 (60 FR 36953), dated July 19, 1995, that codified the criteria for determining the content of TSs. The NRC Committee to Review Generic Requirements reviewed the STs, made note of their safety merits, and indicated its support of conversion by operating plants to the STs. For BVPS-1 and 2, NUREG-1431 documents the STs and forms the basis for the BVPS-1 and 2 conversion to the ITs.

The proposed changes to the CTs are based on NUREG-1431 and the guidance provided in the Final Policy Statement. The objective of this action is to rewrite, reformat, and streamline the CTs (i.e., to convert the CTs to the ITs). Emphasis was placed on human factors principles to improve clarity and understanding.

Some specifications in the CTs would be relocated. Such relocated specifications would include those requirements which do not meet the 10 CFR 50.36 selection criteria. These requirements may be relocated to the TS Bases document, the BVPS-1 and 2 Updated Final Safety Analysis Report, the Core Operating Limits Report, the operational quality assurance plan, plant procedures, or other licensee-controlled documents. Relocating requirements to licensee-controlled documents does not eliminate them, but rather places them under more appropriate regulatory controls (i.e., 10 CFR 50.54(a)(3), and 10 CFR 50.59) to manage their implementation and future changes.

#### *Environmental Impacts of the Proposed Action*

The NRC staff has completed its evaluation of the proposed action and concludes that the conversion to ITs would not increase the probability or consequences of accidents previously analyzed and would not affect facility radiation levels or facility radiological effluents. The proposed action will not increase the probability or consequences of accidents. No changes are being made in the types of effluents that may be

released off site. There is no significant increase in the amount of any effluent released off site. There is no significant increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action does not have a potential to affect any historic sites because no previously undisturbed area will be affected by the proposed amendment. The proposed action does not affect non-radiological plant effluents and has no other effect on the environment. Therefore, there are no significant non-radiological environmental impacts associated with the proposed action.

Accordingly, the NRC staff concludes that there are no significant environmental impacts associated with the proposed action and, thus, the proposed action will not have any significant impact to the human environment.

#### *Environmental Impacts of the Alternatives to the Proposed Action*

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (i.e., the "no-action" alternative). Denial of the application would result in no change in current environmental impacts. Thus, the environmental impacts of the proposed action and the alternative action are similar.

#### *Alternative Use of Resources*

The action does not involve the use of any different resources than those previously considered in the Final Environmental Statement for BVPS-1 and 2 dated July 1973 and September 1985, respectively.

#### *Agencies and Persons Consulted*

In accordance with its stated policy, on January 23, 2007, the NRC staff consulted with the Pennsylvania State official, Lawrence Ryan, of the Pennsylvania Department of Environmental Protection, regarding the environmental impact of the proposed action. The State official had no comments.

#### *Finding of No Significant Impact*

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated June 29, 2005, as supplemented by letters dated February 25, 2005, as supplemented by letters dated November 11, 2005, April 19, September 9, October 24, and December 7, 2006, and the information provided to the NRC staff through the joint NRC/BVPS ITS Conversion web page. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1-800-397-4209 or 301-415-4737, or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov).

Dated at Rockville, Maryland, this 25th day of January 2007.

For The Nuclear Regulatory Commission.

**Nadiyah S. Morgan,**

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## **NUCLEAR REGULATORY COMMISSION**

[Docket Nos. 50-259, 50-260, and 50-296]

### **Tennessee Valley Authority; Browns Ferry Nuclear Plant; Final Environmental Assessment and Finding of No Significant Impact Related to the Proposed License Amendment To Increase the Maximum Reactor Power Level**

**AGENCY:** U.S. Nuclear Regulatory Commission (NRC).

**SUMMARY:** The NRC has prepared a final Environmental Assessment (EA) of its evaluation of a request by the Tennessee Valley Authority (TVA) for license amendments to increase the maximum thermal power at Browns Ferry Nuclear Plant (BFN) from 3458 megawatts-thermal (MWt) to 3952 MWt for Units 2 and 3 and from 3293 MWt to 3952 MWt for Unit 1. These represent power increases of approximately 15 percent for BFN Units 2 and 3 and 20 percent for BFN Unit 1. As stated in the NRC staff's position paper dated February 8,

1996, on the Boiling-Water Reactor (BWR) Extended Power Uprate (EPU) Program, the NRC staff would prepare an environmental impact statement if it believes a power uprate would have a significant impact on the human environment. The NRC staff did not identify any significant impact from the information provided in the licensee's EPU applications for BFN Units 1, 2, and 3 or from the NRC staff's independent review; therefore, as required by Title 10 of the *Code of Federal Regulations* (10 CFR), the NRC staff is issuing this EA and Finding of No Significant Impact.

The NRC published a draft EA and finding of no significant impact on the proposed action for public comment in the **Federal Register** on November 6, 2006 (71 FR 65009). Two sets of comments were received as discussed below.

The licensee provided a comment in a letter dated December 5, 2006 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML063390663). The comment clarified that upon increasing discharge temperatures, TVA would take action to ensure that the discharge temperature would not exceed the National Pollutant Discharge Elimination System (NPDES) permit effluent limitations. The language in the EA has been modified in response to this comment.

The U.S. Department of the Interior, Fish and Wildlife Service provided comments in a letter dated December 13, 2006 (ADAMS Accession No. ML063610349). In the letter, a concern is expressed about any trend toward prolonged higher temperatures and poor water quality conditions in Wheeler Reservoir as a result of the proposed licensing action. The letter indicates that this concern is being addressed by the continuing monitoring programs and data collection implemented by TVA. The letter did not identify any impact on the EA conclusions based on this concern. Therefore, the EA was not modified due to this comment letter.

## Environmental Assessment

### *Plant Site and Environs*

BFN is located on approximately 340 ha (840 ac) of Federally owned land that is under the custody of the TVA in Limestone County, Alabama. The EPU would apply to facilities at the BFN site, which is located in northern Alabama on the northern shore of Wheeler Reservoir, an impoundment of the Tennessee River, at Tennessee River Mile (TRM) 294. The BFN site is approximately 16 km (10 mi) south of

Athens, Alabama; 16 km (10 mi) northwest of Decatur, Alabama; and 48 km (30 mi) west of Huntsville, Alabama.

Land in the vicinity of BFN is used primarily for agriculture. Population densities are low, with no population centers of significance within 16 km (10 mi) of the plant. The site is surrounded to the north and east by rural countryside. It includes open pasture lands, scattered farmsteads, few residents, and little industry within several miles. The terrain is gently rolling with open views to higher elevations to the north. The southern and western sides of the plant site abut the Wheeler Reservoir, which is a wide expanse of open river used for a variety of recreational purposes. The reservoir in the vicinity of the plant site is moderately used by recreational boaters and fishermen. There are no homes within the foreground viewing distance to the north and east. However, adjacent to the plant site several developments have partial views of the site—a small residential development is sited to the northwest and another across the Wheeler Reservoir to the southwest, and the Mallard Creek public use area is directly across the reservoir. A berm, graded during the initial construction of the plant site and containing approximately 2.5 million m<sup>3</sup> (3.3 million yd<sup>3</sup>) of earth excavated to make cooling water channels, lies adjacent to the cooling tower complex and blocks views of the northern and eastern plant areas. Two wildlife management areas—Swan Creek State Wildlife Management Area and Mallard-Fox Creek State Wildlife Management Area—are within 5 km (3 mi) of the BFN site. The Swan Creek Wildlife Management Area includes 1232 ha (3045 ac) of land and 2357 ha (5825 ac) of water surrounded by numerous industrial facilities. The Mallard-Fox Creek State Wildlife Management Area encompasses approximately 593 ha (1483 ac) and is used primarily for small game hunting. The Round Island Recreation Area, a site on the Central Loop of the North Alabama Birding Trail, is located approximately 5.6 km (3.5 mi) upstream of BFN on the northern side of the Tennessee River and provides birding opportunities and boat access.

BFN has two active nuclear reactor units (Units 2 and 3) and one inactive unit (Unit 1). Each unit includes a BWR and a steam-driven turbine generator manufactured by General Electric Company. Each unit originally was licensed for an output of 3293 MWt, with a design net electric rating of 1065 megawatts-electric (MWe). Major construction on BFN, TVA's first nuclear power plant, began in 1967.

Commercial operation began in 1974 for Unit 1, in 1975 for Unit 2, and in 1977 for Unit 3. All three units were shut down in 1985 during a review of the TVA nuclear power program. Unit 2 returned to service in May 1991, and Unit 3 resumed operation in November 1995. Work began in 2002 to bring Unit 1 up to current standards, and the reactor is currently scheduled to restart in 2007.

Wheeler Reservoir on the Tennessee River is the source for cooling water and most of the auxiliary water systems for BFN. The intake forebay is separated from Wheeler Reservoir by a structure with three bays, each with a gate that can be raised or lowered depending on the operational requirements of the plant. Beyond the forebay are 18 intake pumping station bays (6 per reactor unit) each with traveling screens.

The BFN units are normally cooled by pumping water from Wheeler Reservoir into the turbine generator condensers and discharging it back to the reservoir via three large submerged diffuser pipes that are perforated to maximize uniform mixing into the flow stream.

This straight-through flow path is known as "open cycle" or "open mode" operation. As originally designed, the maximum thermal discharge from the once-through cooling water system is directed into the Wheeler Reservoir, with a temperature increase across the intake and discharge of 13.9 °C (25 °F). The flow exits the diffusers and mixes with the reservoir flow. At the edge of the discharge mixing zone, the water temperature is required to be less than 5.6 °C (10 °F) above ambient water temperature.

Through various gates, some of this cooling water can also be directed through cooling towers to reduce its temperature as necessary to comply with environmental regulations. This flow path is known as the "helper mode" operation.

The capability also exists to recycle cooling water from the cooling towers directly back to the intake structure without being discharged to the reservoir. This flow path, known as the "closed mode" of operation, has not been used since the restart of Units 2 and 3 because of difficulties in meeting temperature limits in summer months and problems with equipment reliability. TVA does not anticipate using this mode in the future, and no procedures for operating in this mode currently exist.

In recent years, only Units 2 and 3 have been operated, but because of a combination of system upgrades and improved flow calibrations, the measured total per-unit condenser

cooling water (CCW) flow rate in open mode (with three CCW pumps per unit) has increased. The condenser tubes were replaced with stainless steel tubing that has a larger internal diameter and lower flow resistance. This modification increased flow through the condenser by approximately 6 percent. TVA estimates total intake for three-unit operation in open mode to be 139 m<sup>3</sup>/s (4907 cfs) or 12,000 m<sup>3</sup>/d (3171 million gallons per day).

Because of various system limitations, BFN cannot pass all the CCW through the cooling towers when operating in the helper mode. The fraction of cooling water that cannot be passed through the cooling towers is routed directly to the river. Also, almost all of the cooling water that passes through the cooling towers is returned to the river, but a small amount is lost to the atmosphere during operation. If cooling tower capacity is increased due to the EPU, this consumptive use could increase proportionally. The cooling towers are only operated when necessary, typically a few weeks during the hottest part of the summer (usually July and August), to meet thermal discharge temperature limits.

The residual heat removal service water (RHRSW) system consists of four pairs of pumps located on the intake structure for pumping river water to the heat exchangers in the RHRSW system and four additional pumps for supplying water to the emergency equipment cooling water (EECW) system. The EECW system distributes cooling water supplied by the RHRSW system to essential equipment during normal and accident conditions.

#### *Identification of the Proposed Action*

By letters dated June 25 and June 28, 2004, TVA proposed amendments to the operating licenses for BFN Units 2 and 3 and for BFN Unit 1, respectively, to increase the maximum thermal power level by approximately 15 percent for Units 2 and 3, from 3458 MWt to 3952 MWt, and by approximately 20 percent for Unit 1, from 3293 MWt to 3952 MWt. The change is considered an EPU because it would raise the reactor core power levels more than 7-percent above the originally licensed maximum power levels. This amendment would allow the heat output of the reactors to increase, which would increase the flow of steam to the turbines. This would increase production of electricity and the amount of waste heat delivered to the condensers, and increase the temperature of the water being discharged into the Wheeler Reservoir. On September 8, 1998, the NRC approved license amendments for

power uprates of 5 percent for BFN Units 2 and 3. BFN Units 2 and 3 are currently operating at 105 percent of their originally licensed thermal power (an increase from 3293 MWt to 3458 MWt). Therefore, the proposed EPUs analyzed in this EA are 15 percent for Units 2 and 3 and 20 percent for Unit 1, which is currently licensed to operate at 100 percent of its originally licensed thermal power (3293 MWt).

#### *The Need for the Proposed Action*

The proposed action would meet the increasing demand for bulk power resulting from the economic growth in the TVA service area. Such economic growth is forecasted to continue in the Tennessee Valley region resulting in an estimated average annual increase of 1.6 percent in the regional energy demand over the next 20 years. Such demand increases would exceed TVA's capacity to generate electricity for its customers. The proposed EPUs would add approximately 600 MWe to the historical generating capacity of BFN; such additional capacity should provide a cost-effective means of meeting the projected increased demand. The EPUs can be implemented without substantial capital investment and would not cause the environmental impacts that would occur if construction of a new power-generation facility was sought to meet the region's electricity needs.

#### *Environmental Impacts of the Proposed Action*

At the time of issuance of the operating licenses for BFN, the NRC staff noted that any activity authorized by the licenses would be encompassed by the overall action evaluated in the Final Environmental Statement (FES) for the operation of BFN that was issued in September 1972. This EA summarizes the non-radiological and radiological impacts in the environment that may result from the proposed action of the EPU.

#### **Non-Radiological Impacts**

##### *Land Use Impacts*

The potential impacts associated with land use for the proposed action include effects from construction and plant modifications. While some plant components would be modified, all plant changes related to the EPUs would occur within existing structures, buildings, and fenced equipment yards housing the major unit components. Also, the EPU would use existing parking lots, road access, lay-down areas, offices, workshops, warehouses, and restrooms. Therefore, no land use would change at BFN. Also, no land use

would change along transmission lines (no new lines would be required for EPU), transmission corridors, switch yards, or substations. According to the SEIS for license renewal of BFN, the only significant cultural resources in the proximity of BFN are site 1Li535 and the Cox Cemetery, which was moved to accommodate original construction of the plant. TVA has procedures in place to ensure that the operation of BFN would protect undiscovered historic or archaeological resources, and the proposed action would not change such procedures.

The EPUs and continued operation of BFN Units 1, 2, and 3 would remain in the scope of the original FES, and therefore, the staff concludes potential impacts to land use and to historic and archaeological resources from the proposed action are bounded by the impacts previously evaluated in the FES.

##### *Cooling Tower Impacts*

In support of the EPUs, operation frequency of the cooling towers would likely increase to approximately 7.2 percent of the time to meet thermal discharge requirements of the NPDES permit. The potential impacts from increased use of the cooling towers would be negligible to minor. The impacts would be increased noise directly proportional to the increased usage frequency. The towers may produce more noise and longer periods of noise due to the increased cooling tower operation, but other background noise, such as traffic, insects, frogs, and air conditioners, dominated TVA's June 2001 background noise survey. There are two neighborhoods in close proximity to BFN. The estimated background noise in the two neighborhoods, Paradise Shores and Lakeview, with six cooling towers operating would be approximately 52 and 48 decibels, respectively. These values are below the U.S. Environmental Protection Agency's (EPA's) recommended level of 55 decibels for the annual equivalent sound level day/night. Therefore, noise increases are not expected to have a noticeable effect on nearby residents.

Conclusions reached in NUREG-1437, *Generic Environmental Impact Statement for License Renewal of Nuclear Plants* (GEIS), apply to the proposed action regarding cooling tower impacts on crops, ornamental vegetation, and native plants. The conclusions state that salt drift, icing, fogging, or increased humidity resulting from cooling tower operation would not be significant. These same conclusions apply for the period of operation prior

to entry into the renewed operating license period. Additionally, as stated in the SEIS, the BFN cooling towers would be operated as helper towers and, therefore, would be operated less frequently than at plants with continuous cooling tower operation. However, since the publication of the NRC's SEIS, TVA has proposed a design change for the future sixth cooling tower, which would result in slightly increased frequency of cooling tower operation than the originally planned 20-cell tower. Nonetheless, cooling tower operation at BFN with all three units operating at EPU levels would still be operated less frequently than at plants with continuous cooling tower operation.

Likewise, the conclusion reached in the GEIS regarding aesthetics of cooling tower operation applies to the BFN helper towers. In addition to increased noise, increased operation of cooling towers may have an aesthetic effect in that a visible plume would be detectable more days of the year. However, the conclusions in the GEIS state that continuously operated cooling towers would not have significant effects on visible and audible aesthetics; therefore, the proposed action, including the increased use of helper towers, would not significantly affect aesthetics. This conclusion also applies to operation both prior to the renewed operating license period and during the renewed operating license period.

The proposed EPU would increase the number of days of operation of the cooling towers, which may increase the number of days experiencing background noise, fogging, icing, increased humidity, and a visible plume. Although the frequency of cooling tower operation would increase, the helper towers would be used only intermittently. Therefore, the staff concludes impacts of operating cooling towers would not be significant for the proposed action.

#### *Transmission Facility Impacts*

The potential impacts associated with transmission facilities for the proposed action include changes in transmission line corridor right-of-way maintenance and electric shock hazards due to increased current. No change in right-of-way maintenance, including vegetative management, would occur as a result of the EPU. The proposed EPU would increase the current, which would affect the electromagnetic field, but would not increase the voltage. Because the voltage would not change, there would be no change in the potential for electric shock.

The National Electric Safety Code (NESC) provides design criteria that limit hazards from steady-state currents. The NESC limits the short-circuit current to the ground to less than 5 mA. There would be an increase in current passing through the transmission lines associated with the increased power level of the proposed EPU. The increased electrical current passing through the transmission lines would cause an increase in electromagnetic field strength. Transmission lines would continue to meet applicable shock prevention provisions of the NESC. Although the U.S. has no guidelines for exposure to power frequency electromagnetic fields, Florida and New York have guidelines based on maximum load-carrying conditions. Under conditions of increased EPU currents, TVA transmission lines would continue to meet such guidelines. No data exist to suggest that higher electromagnetic fields adversely affect human health or flora and fauna.

The impacts associated with transmission facilities for the proposed action would not change significantly relative to the impacts from current plant operation. There would be no physical modifications to the transmission lines, transmission line right-of-way maintenance practices would not change, there would be no changes to transmission line rights-of-way or vertical clearances, and electric current passing through the transmission lines would increase only slightly. Therefore, the staff concludes there would be no significant impacts associated with transmission lines for the proposed action.

#### *Water Use Impacts*

Potential water use impacts from the proposed action include hydrological alterations to the Wheeler Reservoir on the Tennessee River and changes to plant water supply. No changes to the plant intake system are expected due to the proposed action; therefore, the volume of intake water would not change. Therefore, the staff concludes that there would be no significant alteration of the hydrology of the Wheeler Reservoir or the plant's water supply.

In addition to the once-through cooling system, BFN has five mechanical draft cooling towers that operate during helper mode. In conjunction with the restart of Unit 1, TVA has committed to building a replacement for the sixth cooling tower; the replacement tower would have a heat removal capacity greater than or equal to that of existing cooling tower #3. BFN typically enters helper mode

during the hot summer months, and the cooling towers are operated only when necessary to meet the NPDES permit's thermal discharge limits. With the restart of Unit 1, if more than six circulating water pumps are operating, some flow must bypass the cooling towers and enter the river directly due to system limitations. Only about 2 percent of the cooling tower flow is not returned to the river due to evaporation and drift. BFN's consumptive water use consists of a negligible, unquantifiable amount that would not change detectably as a result of the EPU. Therefore, the staff concludes there would be no significant impacts to water use in the Wheeler Reservoir or the Tennessee River for the proposed action.

#### *Discharge Impacts*

Potential impacts to the Wheeler Reservoir from the BFN discharge include increased turbidity, scouring, erosion, and sedimentation. These discharge-related impacts apply to open-cycle flow due to the large volume of water discharged to the reservoir. However, since the EPU at BFN would not alter the intake volume of water, no significant change in discharge volume is anticipated. Therefore, no significant impacts from increased turbidity, scouring, erosion, and sedimentation are expected.

Surface runoff and wastewater discharges at BFN are regulated by the State of Alabama via a NPDES permit (NPDES No. AL0022080). The permit is periodically reviewed and renewed by the ADEM. With the exception of discharge temperature, the EPU would not be expected to alter any other effluents, such as yard drainage, station sumps, and sewage treatment. Increase in discharge temperature in the Wheeler Reservoir would remain within the NPDES permit limits due to the implementation of cooling towers in helping mode or derating the units during hot summer months.

BFN's current NPDES permit limits thermal discharge, as detected at a depth of 5 feet at the end of a 2400-foot mixing zone downstream of the discharge diffusers, to a maximum 1-hour average of 93 °F, a maximum 24-hour average of 90 °F, and a maximum increase of 10 °F over ambient temperatures. Currently with Units 2 and 3 operating at 105 percent of the originally licensed maximum power level in open mode, the approximate temperature increase at the end of the mixing zone is 5.3 °F. Operation of all three units at 120-percent power is predicted to increase the mean water temperature at the end of the mixing

zone by about 0.5 °F compared to current operations and only 0.3 °F when compared to all three units operating at their original power level as assessed in the FES. Increase in discharge temperature approaching the NPDES limits would trigger operation of the cooling towers in helper mode. If operation of the cooling towers is insufficient to reduce discharge temperature enough to remain within the NPDES compliance, the units would be derated so that the discharge temperature does not exceed the permit's limits. It is estimated that three-unit operation with the EPU would increase cooling-tower-operation frequency to about 7.2 percent and would result in derating approximately 0.29 percent of the time. It is expected that such operational controls would maintain compliance with the NPDES permit. When the plant is operating within the permit limits, it is expected that thermal discharge would not have significant individual or cumulative effects on reservoir stratification, dissolved oxygen concentrations, and eutrophication.

The proposed EPU would not result in changes in any other effluents, which are currently within permit limits. Therefore, the staff concludes that the proposed action would not result in any significant impacts on the Wheeler Reservoir or the Tennessee River from BFN discharge.

#### *Impacts on Aquatic Biota*

The potential impacts to aquatic biota from the proposed action include impingement, entrainment, thermal discharge effects, and impacts due to transmission line right-of-way maintenance. The BFN has intake and discharge structures on the Wheeler Reservoir. The aquatic species evaluated in this EA are those in the vicinity of the intake and discharge structures.

Entrainment and impingement of aquatic species at BFN are limited by the NPDES permit. TVA conducted a pre-operational and operational study to collect data describing ichthyoplankton populations in the Wheeler Reservoir from 1971 through 1979. The results of the study indicated that, under open-cycle, three-unit operation, entrainment would not increase mortality significantly beyond the expected levels of natural mortality of fish eggs and larvae and that impingement would not adversely affect the fish community in the Wheeler Reservoir. TVA also conducted flow studies at BFN; the studies indicated that most entrained water originates on the eastern side of the main river channel. This area has lower densities of fish larvae than in

overbank areas. Fish eggs (mostly from freshwater drum [*Aplodinotus grunniens*]) are found in the main channel at higher densities, but abundance of freshwater drum has not decreased noticeably. With the return of three-unit operation at 120-percent power for each unit, entrainment and impingement would increase slightly due to the increased flow rate of CCW. TVA's Vital Signs monitoring program currently being conducted would continue after the return of three-unit operation. In addition to assessing impacts from entrainment and impingement of fish populations in the Wheeler Reservoir, the monitoring program addresses effects on fish population dynamics and commercial and recreational fisheries as needed. The staff has determined that slight increases in entrainment and impingement as a result of the proposed action would not have significant impacts on species abundance or on the Wheeler Reservoir fish community.

On July 9, 2004, EPA published a final rule in the **Federal Register** (69 FR 41575) addressing cooling water intake structures at existing power plants whose flow levels exceed a minimum threshold value of 50 million gallons per day. The rule is Phase II in EPA's development of 316(b) regulations that establish national requirements applicable to the location, design, construction, and capacity of cooling water intake structures at existing facilities that exceed the threshold value for water withdrawals. The national requirements, which are imposed with NPDES permits, minimize the adverse environmental impacts associated with the continued use of the intake systems. Licensees are required to demonstrate compliance with the Phase II performance standards to renew their NPDES permits. TVA is currently conducting entrainment and impingement studies at BFN in compliance with the Phase II rule.

Fish have the ability to detect thermal changes and actively avoid areas with elevated water temperature near the BFN diffusers. Thermal modeling shows that the bank opposite the BFN diffusers would not be affected by the thermal plume and, therefore, would allow passage for migrating fish. Known fish hosts for the protected freshwater mussels (see section below describing impacts on threatened and endangered species) are common in the Wheeler Reservoir. Most fish host species in the reservoir have upper lethal temperature limits that are higher than the BFN thermal variance of 90 °F. Studies on the least thermally tolerant species, sauger (*Stizostedion vitreum*) and

yellow perch (*Perca flavescens*), showed that BFN had no significant, adverse impacts on reproduction of either species or on the annual sauger migration past BFN for spawning (Baxter and Buchanan 1998). Most larvae and eggs drifting past BFN are demersal and would have very little exposure to the thermal plume due to rapid mixing with the ambient surface water and rising of the heated water. Therefore, the thermal plume associated with the proposed EPU is not expected to affect adversely any life history stages of freshwater mussels or their host species.

The NPDES permit limits the amount of heat discharged to the Wheeler Reservoir from the operation of BFN. The thermal limits specified in the NPDES permit (as discussed above in discharge impacts section) would not change with implementation of the EPU. Because TVA would continue to meet the thermal limits set in the NPDES permit, whether in open cycle, in helper mode, or via power derating, the proposed action is not expected to result in additional thermal discharge effects on aquatic species in the Wheeler Reservoir.

As discussed in the transmission facility impacts section of this EA, transmission line right-of-way maintenance practices would not change for the proposed action. Therefore, the staff concludes that there would be no significant impacts to aquatic species associated with transmission line right-of-way maintenance for the proposed action.

#### *Impacts on Terrestrial Biota*

The proposed action would not include any new land disturbance or changes in transmission line right-of-way maintenance. Most areas at BFN are not pristine and continue to provide habitat only for species with widespread distributions; the wildlife diversity at BFN is not great. No rare terrestrial species occur in the vicinity of BFN. Although wetlands do occur at the BFN site (25 acres according to the National Wetlands Inventory and 12 acres according to the Federal jurisdictional criteria), none of the wetlands would be affected by the proposed action. Therefore, the staff concludes that there would be no significant impacts to terrestrial species or their habitat associated with the proposed action, including transmission line right-of-way maintenance.

#### *Impacts on Threatened and Endangered Species*

Potential impacts to threatened and endangered species from the proposed

action include the impacts assessed in the aquatic and terrestrial biota sections of this environmental assessment. These impacts include impingement, entrainment, thermal discharge effects, and impacts due to transmission line right-of-way maintenance for aquatic and terrestrial species.

There are seven species listed as threatened or endangered under the Federal Endangered Species Act that occur within Limestone County, Alabama. The listed terrestrial species include the endangered gray bat (*Myotis grisescens*) and the endangered Indiana bat (*M. sodalis*). These two species are not known to occur within three miles of BFN. As no significant impacts are expected to terrestrial species or their habitat, the proposed action would not have significant impacts on the gray or Indiana bats or their habitats.

There are five Federally endangered aquatic species that occur within the vicinity of BFN. The rough pigtoe (*Pleurobema plenum*) and the pink mucket (*Lampsilis abrupta*) are freshwater mussels that have been reported to occur in areas upstream from BFN. It is unlikely that these species would occur in areas near the thermal plume or downstream of BFN; therefore, effects on the rough pigtoe, the pink mucket, their habitats, or their fish host species (see aquatic biota section above describing impacts on host species) are not expected to result from the proposed action. The three other Federally listed aquatic species are endangered snails: armored snail (*Pyrgulopsis pachyta*), slender campeloma (*Campeloma decampi*), and Anthony's river snail (*Atheurnia anthonyi*). All three Federally endangered aquatic snails are found only in tributaries to the Wheeler Reservoir that are located upstream of BFN; therefore, no significant impacts on these snails are expected from the proposed action. No Federally listed fish species or critical habitat are known to occur within the vicinity of BFN. TVA's Vital Signs monitoring program and Regional Natural Heritage Program would continue acting as tools for identification of protected species and habitat at BFN. The staff concludes that there would be no significant effects on Federally threatened or endangered

species as a result of the proposed action.

#### Socioeconomic Impacts

Potential social and economic impacts due to the proposed action include changes in the payments in lieu of taxes for Limestone County and changes in the size of the workforce at BFN. The NRC staff has reviewed the information provided by the licensee regarding socioeconomic impacts. Because BFN changes in conjunction with the proposed action would occur during a planned outage, the proposed action would not result in any additional changes in the workforce. For all planned outages, which typically last about 35 days, employment at BFN would increase by about 1000 people at most. Due to the short-term need for increased employment, it is not expected that workers would move into the local area for such temporary employment. The maximum employment during an outage would be about 3.1 percent of Limestone County's current labor force, which was about 32,690 in 2003. For the primary labor market area, which includes Huntsville, Decatur, and Florence, BFN outages would employ about 0.3 percent of the labor force, which was about 318,800 in 2003. Therefore, the proposed EPU would not affect significantly the size of the BFN labor force as the modifications would occur during planned outages and would not increase the size of permanent employment at BFN. Accordingly, the proposed action would not have measurable effects on annual earnings and income in Limestone County or on community services due to the very small and insignificant impact on the local population.

The Limestone County population is about 17.6 percent minority, which is well below both the state and national minority populations, 29.7 and 30.9 percent, respectively. The labor market minority population is about 22.1 percent. The poverty rates in Limestone County and the labor market area are 12.3 percent and 12.1 percent, respectively, which are lower than the state's average of 16.1 percent and about the same as the nation's average of 12.4 percent. Therefore, due to the low minority population, low poverty rate, and lack of significant environmental impacts resulting from the proposed

action, the proposed EPU would not have disproportionate negative impacts to minority and low-income populations.

In compliance with Section 13 of the TVA Act, TVA makes payments in lieu of property taxes to states and counties in which its power operations occur and in which its acquired properties were subject to state and county taxation previous to their acquisition by TVA. For such payments, TVA pays 5 percent of its gross power revenues to appropriate states and counties, with most of the money paid to the states, which redistribute the payments to local governments. The proposed action would affect the in-lieu-of-tax payments because the total amount of money to be distributed increases as power generation increases and because the EPU would increase BFN's value, thus resulting in a larger allocation of the payment to Limestone County. Because the proposed EPU would increase the economic viability of BFN, the probability of early plant retirement would be reduced. Early plant retirement would be expected to have negative impacts on the local economy and the community by reducing in-lieu-of-tax payments and limiting local employment opportunities for the long term.

While the proposed action would not affect the labor force significantly, there would be no disproportionate impacts on minority or low-income populations. Additionally, the proposed EPU would increase the in-lieu-of-tax payments received by Limestone County, increase the book value of BFN, and increase the long-term viability of BFN. Therefore, the staff concludes that there would be no significant socioeconomic impacts associated with the proposed action.

#### Summary

The proposed EPU would not result in a significant change in non-radiological impacts in the areas of land use, cooling tower operation, transmission facility operation, water use, waste discharges, aquatic and terrestrial biota, or socioeconomic factors. No other non-radiological impacts were identified or would be expected. Table 1 summarizes the non-radiological environmental impacts of the proposed EPU at BFN.

TABLE 1.—SUMMARY OF NON-RADIOLOGICAL ENVIRONMENTAL IMPACTS

Land Use .....	No significant land-use modifications.
Cooling Tower .....	No significant aesthetic impacts; slightly larger visible plume and increased noise due to more frequent operation; no significant fogging or icing.

TABLE 1.—SUMMARY OF NON-RADIOLOGICAL ENVIRONMENTAL IMPACTS—Continued

Transmission Facilities .....	No physical modifications to transmission lines; lines meet shock safety requirements; no changes to right-of-ways; small increase in electrical current would cause small increase in electromagnetic field around transmission lines; no changes to voltage.
Water Use .....	No configuration change to intake structure; no increased volume of water withdrawal; increase in flow rate of condenser cooling water; slight increase in consumptive use due to evaporation; no water use conflicts.
Discharge .....	Increase in discharge water temperature; no increases in other effluents; discharge would remain within NPDES permit limits due to cooling tower operation and derating as necessary.
Aquatic Biota .....	Entrainment and impingement would increase slightly but are not expected to affect the fish community in Wheeler Reservoir.
Terrestrial Biota .....	No land disturbance or changes to transmission line right-of-way maintenance are expected; therefore, there would be no significant effects on terrestrial species or their habitat.
Threatened and Endangered Species .....	As for aquatic and terrestrial biota, no significant impacts are expected on protected species or their habitat.
Socioeconomics .....	No significant change in size of BFN labor force required for plant operation or for planned outages; proposed EPU would increase in-lieu-of-tax payments to Limestone County and book value of BFN; minority and low-income populations would not be disproportionately affected.

## Radiological Impacts

### *Radioactive Waste Stream Impacts*

BFN uses waste treatment systems designed to collect, process, and dispose of gaseous, liquid, and solid wastes that might contain radioactive material in a safe and controlled manner such that discharges are in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection Against Radiation,” and 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” Appendix I. Although there may be a small increase in the volume of radioactive waste and spent fuel, the proposed EPU would not result in changes in the operation or design of equipment in the gaseous, liquid, or solid waste systems.

### *Gaseous Radioactive Waste and Offsite Doses*

During normal operation, the gaseous effluent treatment systems process and control the release of gaseous radioactive effluents to the environment, including small quantities of noble gases, halogens, tritium, and particulate material. The gaseous waste management systems include the offgas system and various building ventilation systems. The proposed EPU is expected to result in a 15–20 percent increase in gaseous effluents, which is still well within regulatory limits of Appendix I to 10 CFR Part 50. Therefore, the increase in offsite dose due to gaseous effluent release following the EPU would not be significant.

### *Liquid Radioactive Waste and Offsite Doses*

During normal operation, the liquid effluent treatment systems process and control the release of liquid radioactive effluents to the environment, such that

the doses to individuals offsite are maintained within the limits of 10 CFR Part 20 and 10 CFR Part 50, Appendix I. The liquid radioactive waste systems are designed to process the waste and then recycle it within the plant as condensate, reprocess it through the radioactive waste system for further purification, or discharge it to the environment as liquid radioactive waste effluent in accordance with State and Federal regulations. Although no changes to the liquid radioactive waste processing and disposition at BFN are expected to occur with the EPU, TVA does expect a small increase in the volume to be processed. The projected liquid effluents would be well within the regulatory limits under the proposed action. Therefore, there would not be a significant environmental impact from the additional volume of liquid radioactive waste generated following the EPU.

### *Solid Radioactive Wastes*

The solid radioactive waste system collects, processes, packages, and temporarily stores radioactive dry and wet solid wastes prior to shipment offsite and permanent disposal. The proposed EPU would generate 15–20 percent more radioactive resin, resulting from the increased condensate demineralizer flow. Such an increase would not exceed BFN’s capacity for radioactive waste treatment and storage. Modifications associated with the proposed action would generate a small amount of dry radioactive waste, which would remain within the range of solid waste currently generated and would not impact waste generation goals.

The proposed action would increase the average batch size of fuel assemblies for refueling, but it would not affect BFN’s schedule for spent fuel storage expansion. The number of dry storage

casks required with the proposed EPU would increase by about 7 percent. Therefore, the increase in solid radioactive waste under the proposed action would not have a significant environmental impact.

### *In-Plant Radiation Doses*

The proposed EPU would result in the production of more radioactive material and higher radiation dose rates in some areas at BFN. The annual average occupational radiation dose to an individual for BFN during the 1991-to-2000 period was 0.198 rem. The predicted occupational radiation dose for BFN with the proposed EPU could increase to almost 0.24 rem, which is about 5 percent of the 10 CFR part 20 limit for adult whole body occupational radiation dose. This estimate does not account for potential further reductions in dose due to As Low As Reasonably Achievable program initiatives and administrative dose level controls. Therefore, the proposed action is not expected to impact significantly the in-plant radiation doses.

### *Direct Radiation Doses Offsite*

Direct radiation from radionuclides (mainly nitrogen-16) in the reactor water and the turbine building would increase linearly with the EPU. Such increase in radiation would be monitored at the on-site environmental thermoluminescent dosimeter (TLD) stations at BFN. In the past, data from BFN’s TLD stations have not indicated that any measurable nitrogen-16 radiation could be detected off site. Therefore, it is unlikely that the small increase in radiation associated with the EPU would result in any measurable dose to the public.

The annual whole body dose equivalent for liquid effluents to a member of the public beyond the site boundary is limited to 25 mrem (0.25



mSv) by 40 CFR 190. The projected maximum direct radiation dose offsite at BFN with the EPU is 0.065 mrem, which is only about 0.3 percent of the limit in 40 CFR 190. The liquid effluent dose limit for any organ is projected to be 0.94 mrem/year, which is only 0.4 percent of the 40 CFR 190 limit. Projected gaseous limits with the EPU would also remain well within limits, with each dose type reaching less than 0.2 percent of the limit. The licensee would continue to perform surveys as the EPU is implemented to ensure continued compliance with 40 CFR 190. Therefore, the direct radiation dose offsite at BFN with the EPU would not be significant and is not expected to affect human health.

#### *Postulated Accident Doses*

As a result of implementation of the proposed EPU, there is an increase in the source term used in the evaluation of some of the postulated accidents in the FES. The inventory of radionuclides in the reactor core is dependent upon power level; therefore, the core inventory of radionuclides could increase by as much as 20 percent. The concentration of radionuclides in the reactor coolant may also increase by as much as 20 percent; however, this concentration is limited by the BFN Technical Specifications. Therefore, the reactor coolant concentration of radionuclides would not be expected to increase significantly. This coolant concentration is part of the source term considered in some of the postulated accident analyses. Some of the radioactive waste streams and storage systems evaluated for postulated accidents may contain slightly higher quantities of radionuclides.

In 2002, TVA requested a license amendment to allow the use of Alternate Source Term (AST) methodology for design basis accident analyses for BFN Units 1, 2, and 3. TVA conducted full-scope AST analyses, which considered the core isotopic values for the current and future vendor products under EPU conditions. TVA concluded that the calculated post-accident offsite doses for the EPU using AST methodologies meet all the applicable acceptance criteria of 10 CFR 50.67 and Regulatory Guide 1.183. The NRC staff is reviewing the licensee's analyses and performing confirmatory calculations to verify the acceptability of the licensee's calculated doses under accident conditions. The results of the NRC staff's calculations will be presented in the safety evaluation to be issued with the license amendment, and the EPU would not be approved by NRC unless the NRC staff's independent review of dose calculations under postulated accident conditions determines that dose is within regulatory limits. Therefore, the NRC staff concludes that the EPU would not significantly increase the consequences of accidents and would not result in a significant increase in the radiological environmental impact of BFN from postulated accidents.

#### *Fuel Cycle and Transportation Impacts*

The environmental impacts of the fuel cycle and transportation of fuels and wastes are described in Tables S-3 and S-4 of 10 CFR 51.51 and 10 CFR 51.52, respectively. An additional NRC generic EA (53 FR 30355, dated August 11, 1988, as corrected by 53 FR 32322, dated August 24, 1988) evaluated the applicability of Tables S-3 and S-4 to higher burn-up cycle and concluded

that there is no significant change in environmental impact from the parameters evaluated in Tables S-3 and S-4 for fuel cycles with uranium enrichments up to 5 weight percent uranium-235 and burn-ups less than 60,000 MWt days per metric ton of uranium-235 (MWd/MTU). Resulting from an interagency agreement in 2001 between TVA and the Department of Energy, 33 metric tons of highly enriched uranium will be obtained and blended down to allow use of the low enriched uranium as nuclear reactor fuel for BFN. With the use of blended low enriched uranium fuel, a higher percentage of uranium-236 exists. As a neutron poison, uranium-236 requires greater enrichment to compensate for reactivity loss. The number of fuel assemblies to be shipped would increase as would the associated handling doses. However, the burn-up limit and the uranium enrichment limit would stay within the 5 percent and the 60,000 MWd/MTU limits. Therefore, the environmental impacts of the EPU would remain bounded by the impacts in Tables S-3 and S-4 and would not be significant.

#### *Summary*

The proposed EPU would not significantly increase the consequences of accidents, would not result in a significant increase in occupational or public radiation exposure, and would not result in significant additional fuel cycle environmental impacts. Accordingly, the Commission concludes that there would be no significant radiological environmental impacts associated with the proposed action. Table 2 summarizes the radiological environmental impacts of the proposed EPU at BFN.

TABLE 2.—SUMMARY OF RADIOLOGICAL ENVIRONMENTAL IMPACTS

Gaseous Effluents and Doses .....	Slight increase (by about 15–20 percent) in dose due to gaseous effluents; doses to individuals offsite would remain within NRC limits.
Liquid Effluents and Doses .....	Volume of liquid effluent generated and amount of radioactivity in the effluent are expected to increase slightly; discharges of liquid effluents would remain within NRC limits; however, no routine discharge of liquid effluent is expected.
Solid Radioactive Waste .....	Volume of solid waste expected to increase slightly due to more frequent change of demineralizer resins; increase in amount of spent fuel assemblies.
In-plant Dose .....	Occupational dose could increase by 20 percent overall; occupational doses would remain well within NRC limits.
Direct Radiation Dose .....	Up to 20 percent increase in production of nitrogen-16; however, dose rate at site boundary due to skyshine is not expected to increase significantly and would remain within NRC and EPA limits.
Postulated Accidents .....	Licensee using AST; doses would remain within NRC limits.
Fuel Cycle and Transportation .....	Impacts in Tables S-3 and S-4 in 10 CFR 51, "ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTION" are bounding.



### Alternatives to Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed EPU (i.e., the “no-action” alternative). Denial of the application would result in no change in the current environmental impacts. However, if the EPU were not approved, other agencies and electric power organizations may be required to pursue other means of providing electric generation capacity to offset future demand. Fossil fuel plants routinely emit atmospheric pollutants, causing impacts in air quality that are larger than if BFN were to provide the same amount of electric generation. Construction and operation of a fossil fuel plant also create impacts in land use and waste management. Other alternatives, such as purchased electrical power, wind power, and hydropower, were considered during the NRC’s review for the BFN license renewal. The proposed EPU, like license renewal, would incur fewer environmental costs than the alternatives considered. While the EPU would produce additional spent fuel, the additional amount of spent fuel would be stored in a new dry cask storage facility, which would be constructed even if the EPU were not approved. Therefore, the proposed EPU would not have significant environmental impacts.

### Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the SEIS.

### Agencies and Persons Consulted

In accordance with its stated policy, on August 7, 2006, the NRC staff consulted with the Alabama State official, Mr. Kirk Whatley, of the Office of Radiation Control, regarding the environmental impacts of the proposed action. The State official had no comments.

### Finding of No Significant Impact

On the basis of the EA, the Commission concludes that the proposed action would not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an Environmental Impact Statement for the proposed action.

For further details with respect to the proposed action, see the licensee’s applications dated June 25 and June 28, 2004, as supplemented by letters dated August 23, 2004, February 23, April 25, June 6, and December 19, 2005, February 1 and 28, March 7, 9, 23, and 31, April 13, May 5 and 11, June 12, 15,

23 and 27, July 21, 26, and 31, August 4, 16, 18, and 31, September 1, 15, and 22, and October 3, 5, and 13, 2006. Documents may be examined, and/or copied for a fee, at the NRC’s Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff at 1-800-397-4209, or 301-415-4737, or send an e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov).

Dated at Rockville, Maryland, this 6th day of February 2007.

For the Nuclear Regulatory Commission.

**Timothy J. McGinty,**

*Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

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## NUCLEAR REGULATORY COMMISSION

### Final Regulatory Guides: Impending Issuance, Availability, and Applicability to New Reactor Licensing

**AGENCY:** U.S. Nuclear Regulatory Commission.

**ACTION:** Issuance, Availability, and Applicability of Final Regulatory Guides for New Reactor Licensing.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is currently reviewing and revising numerous guides in the agency’s Regulatory Guide (RG) Series. This series has been developed to describe, and make available to the public, methods that are acceptable to the NRC staff for implementing specific parts of the NRC’s regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

### Availability And Dates

The NRC will make each new or revised RG publicly available through the following electronic distribution channels:

- The NRC’s Electronic Reading Room on the agency’s public Web site, in the Regulatory Guides document

collection, at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>.

- The NRC’s Agencywide Document Access and Management System (ADAMS), at <http://www.nrc.gov/reading-rm/adams.html> (using the ADAMS accession number specified in the footer on the first page of each regulatory guide).

Please note that the NRC does not intend to distribute printed copies of these revised RGs unless specifically requested on an individual basis with adequate justification. Requests for single copies should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Reproduction and Distribution Services Section; by e-mail to [DISTRIBUTION@nrc.gov](mailto:DISTRIBUTION@nrc.gov); or by fax to (301) 415-2289. Telephone requests cannot be accommodated. In addition, the NRC does not intend to issue separate notices of issuance and availability. Consequently, interested parties should regularly peruse the previously specified electronic distribution channels to identify newly revised RGs.

RGs are not copyrighted, and Commission approval is not required to reproduce them. Copies of each RG and other related publicly available documents, including public comments received, can be viewed electronically on computers in the NRC’s Public Document Room (PDR), which is located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland, Room O-1 F21, and is open to the public on Federal workdays from 7:45 a.m. until 4:15 p.m. The PDR reproduction contractor will make copies of documents for a fee. Selected documents, including public comments on the DGs, can also be viewed and downloaded electronically via ADAMS at <http://www.nrc.gov/NRC/reading-rm/adams.html>. If you do not have access to ADAMS or if you encounter problems in accessing the documents stored in ADAMS, contact the PDR Reference Staff at (800) 397-4209 or (301) 415-4737, or by e-mail to [PDR@nrc.gov](mailto:PDR@nrc.gov).

**SUPPLEMENTARY INFORMATION:** The revised versions of the RGs will not be used as a backfit to any previously issued staff position for existing nuclear power reactors. The purpose of the ongoing revision of the NRC’s RGs is to ensure that prospective applicants have complete, accurate, and current guidance for use in preparing early site permit (ESP), design certification (DC), and combined license (COL) applications for proposed new reactors. In particular, the NRC staff ensures that the agency’s regulatory guidance is