NRC104

HITACHI

Albert E. Kennedy, Manager
GLE Environmental, Health, & Safety
P. O. Box 780 – M/C L-65
Wilmington, NC 28402 USA
T 910-819-1925
F 910-342-5925
AlbertE.Kennedy@ge.com

MFN-09-801
December 28, 2009

Attn: Document Control Desk
Brian Smith, Chief
Uranium Enrichment Branch
Fuel Facility Licensing Directorate
Division of Fuel Cycle Safety & Safeguards
Office of Nuclear Materials Safety & Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: **RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION DATED NOVEMBER 19, 2009 FOR GLOBAL LASER ENRICHMENT LICENSE APPLICATION – PUBLIC RESPONSES**

Dear Mr. Smith:

GE-Hitachi Global Laser Enrichment LLC (GLE) hereby submits the additional information requested in the November 19, 2009 letter. Enclosure 1 of this letter contains the responses the questions. A separate letter has been submitted that contains a non-public version of these responses, which contains Export-Controlled and Security-Related Information.

If there are any questions regarding this letter and its contents, please do not hesitate to contact myself, or Julie Olivier of my staff at 910-819-4799 or at Julie.Olivier@ge.com.

Sincerely,

Julie A. Olivier for AEK

Albert E. Kennedy
Manager, GLE Environmental, Health, & Safety

References:

1. Letter, Brian Smith (NRC) to Julie Olivier (GLE), "REQUEST FOR ADDITIONAL INFORMATION – GENERAL ELECTRIC-HITACHI GLOBAL LASER ENRICHMENT LICENSE APPLICATION", November 19, 2009.

Enclosures:

1. Response to November 19, 2009 NRC letter

Cc (without enclosures):
Tim Johnson (NRC)
Tammy Orr (GLE)
Lori Butler (GEH)
Jerry Head (GEH)
Patricia Campbell (GEH)
Bob Crate (GLE)
Ken Givens (GLE)
Tom Owens (GLE)
MFN-09-801

Enclosure 1
Responses to November 19, 2009 Request for Additional Information
Public Responses (MFN-09-801)

General Information (Chapter 1)

GI-1 General

Clarify the enrichment level the applicant intends to produce at the facility.

Recent discussions with the applicant suggest that the enrichment level may be changed. The enrichment level of the facility is needed to ensure that adequate nuclear criticality safety provisions are in place.

The regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(a)(2) requires that the license application describe the activity in which Special Nuclear Material (SNM) will be produced.

<u>GLE Response</u>

The target enrichment limit for the GLE facility will initially be 5 wt% ^{235}U. This is the maximum product enrichment that is intended to be produced in the process based on current industry demand. Criticality safety for the GLE facility has been demonstrated at up to 8 wt% ^{235}U, which provides adequate safety margin under postulated credible enrichment upset conditions. GLE has determined that the enrichment safety limit of 8 wt% ^{235}U will not be exceeded under credible process upset conditions if the target enrichment process limit is restricted to 5 wt% ^{235}U. The basis for this conclusion has been documented internally and made available for NRC review.

At present the process-upset conditions that have been deemed "credible" are very conservative, as are the various assumptions that affect the calculated maximum enrichment under these conditions. In the future, GLE may revise these calculations to determine a more accurate (yet still conservative) estimate of the maximum enrichment under credible upset conditions. This more detailed, and accurate, evaluation could be used to demonstrate that the enrichment safety limit of 8 wt% ^{235}U will not be exceeded if the target enrichment process limit is elevated to a level above 5 wt% ^{235}U. Furthermore, criticality safety analysis may be performed to demonstrate safety at greater than 8 wt% ^{235}U in order to demonstrate it is safe to use a target enrichment process limit is in excess of 5 wt% ^{235}U.

Although there is no industry demand for material enriched in excess of 5 wt% ^{235}U at present, there is the potential for that to change in the foreseeable future. As a result, GLE is proposing a license limit of 8 wt% ^{235}U, with an initial operating limit of 5 wt% ^{235}U. In the event that GLE decides there is a need to produce product in excess of 5 wt% ^{235}U, and demonstrates it can be safely produced, the NRC would be notified well in advance and provided the documented safety basis for the change. GLE proposes this notification requirement be addressed through a license conditions similar to that provided to other license applicants (NUREG-1851, SNM-2011). It should be noted that such a change would also be subject to the 10 CFR 70.72 process to determine if the change requires NRC approval, or license amendment, per the specified criteria.

License Documentation Impact

GLE does not propose any changes to the current license application but does anticipate a license condition similar to the following;

"GLE shall provide a minimum 60-day notice to NRC prior to initial customer product withdrawal of licensed material exceeding 5 wt. percent 235U enrichment. This notice shall identify the necessary equipment and operational changes to support customer product shipment for these assays."

GI-2 Section 1.1.2.1.1

Clarify whether or not SNM will be used in the cylinder shipping and receiving area.

Section 1.1.2.1.1 of the License Application (LA), states that this area will provide interim storage of product, feed, and sample/blend cylinders. At the end of this section, it only states that source material is used in this area, however, SNM should also be identified.

Regulations in 10 CFR 70.22(a)(2) require the license application to describe how SNM is to be used.

GLE Response

The statement made at the end of Section 1.1.2.1.1 of the license application is incorrect. Both source material and SNM are present in the cylinder shipping and receiving area. Natural and tails UF_6 in standard 48-inch cylinders may be present in the area for various shipping and receiving operations. In addition, the area provides interim storage for product 30B cylinders containing SNM and stages these cylinders for offsite transport or onsite transfer. The area also provides interim storage for 48GLE cylinders containing SNM. These operations are described in detail in Section 1.1.2.1.1 of the license application.

License Documentation Impact

The last sentence in Section 1.1.2.1.1 of the license application will be revised to include the following statement:

"Source material and SNM are used in this area."

GI-3 Section 1.1.2.1.2

Explain why Section 1.1.2.1.2 states that SNM is used in the Feed and Vaporization area.

Section 1.1.2.1.2 states that both source and SNM will be used in the Feed and Vaporization Area. However, the use of SMN in this area would not normally be expected.

Regulations in 10 CFR 70.22(a)(2) require the license application to describe how SNM is to be used.

GLE Response

The statement made at the end of Section 1.1.2.1.2 of the license application is incorrect. Only source material is used in the feed and vaporization area. Natural or tails UF_6 may be fed to the enrichment cascade from standard 48-inch cylinders. Enriched material (i.e., SNM) is not permitted for use as feed to the enrichment cascade and is not permitted in this area. In addition, IROFS that prevent the feed of enriched material to the system have been identified and are specified in Section 4.3.6.4 of the ISA summary.

License Documentation Impact

The last sentence in Section 1.1.2.1.2 of the license application will be revised as follows:

"*Source material ~~and SNM~~ is used in this area.*

GI-4 Section 1.1.2.1.3

Identify the appropriate cylinders for enriched product for U-235 assays between 5 and 8 percent.

In the fourth bullet on p. 1-9, General Electric-Hitachi (GEH) Global Laser Enrichment states it will fill 30- and 48-inch cylinders with up to 8 percent enriched uranium. Note that 30- and 48-inch cylinders have enrichment limits between 1 and 5 percent depending on the cylinder type and its use and would be unacceptable for U-235 assays above those limits.

Regulations in 10 CFR 70.22(a)(7) and (8) require the applicant to describe the equipment, facilities, and procedures that will be used to protect health and minimize danger to life and property.

GLE Response

UF_6 cylinders used in the CF include:

- *Model 30B*
  - *Currently approved for interim storage and offsite shipment of enriched UF_6 limited to ≤ 5.00 wt% ^{235}U; and*
  - *Analyzed for interim storage of enriched UF_6 limited to ≤ 8.00 wt% ^{235}U (CSA 4100.01,* 30B UF_6 Cylinder Storage*);*
- *Model 48Y*
  - *Currently approved for receipt and storage of UF_6 feed enriched to ≤ 1.00 wt% ^{235}U (typically natural UF_6) from supplier;*
  - *Currently approved for offsite shipment of heels, tails and empty cylinders back to supplier; and*

- *Analyzed for onsite storage of enriched UF_6 limited to ≤ 8.00 wt% ^{235}U (CSA 4100.02,* 48-inch UF_6 Cylinder Storage*)*

- *Model 48G*
  - *Currently approved for interim storage and offsite shipment of UF_6 "tails" ≤ 0.72wt% ^{235}U enrichment*

- *Model 48GLE*
  - *Analyzed for interim storage of enriched UF_6 limited to ≤ 8.00 wt% ^{235}U (CSA 4300.00,* UF_6 Product Withdrawal*); and*
  - *Analyzed for Blending activities.*

The model 48GLE UF_6 cylinder is a modified Model 48Y UF_6 cylinder designed to ANSI-14.1 with modifications to the cylinder outside rib structure and equipped with a different valve designed to prevent the use of these cylinders in the place of a 48Y or 48G cylinders as an enrichment control.

For clarification, the first and fourth bullet in Section 1.1.2.1.3 will be changed to reflect that 48GLE cylinder may contain UF_6 with enrichments up to 8.00 wt% ^{235}U and restricted to onsite use only. Note that offsite transport of the 48GLE UF_6 cylinder is not approved per DOT regulation and GLE does not intend to transport any UF_6 cylinder with enrichments > 5.0 wt% ^{235}U over public roadways.

License Documentation Impact

GLE will revise LA, Chapter 1, Section 1.1.2.1.3 as follows:

1.1.2.1.3 Product Withdrawal Area

The Product Withdrawal Area contains the necessary equipment to perform the following functions:

- Receive empty 48GLE UF_6 cylinders from interim storage within the Cylinder Shipping and Receipt Area;
- Maintain design basis UF_6 product withdrawal rates from the Cascade main discharge header;
- Separate the light gases from the UF_6 for disposal; and
- Provide filled ~~30- and 48-inch~~48GLE UF_6 cylinders with ≤ 8.00 wt% ^{235}U for onsite use only (blending activities and interim storage).

The Product Withdrawal Area contains: volume reducing compressor trains (VRCTs) that move UF_6 product material from the Cascade/Gas Handling System to the product Withdrawal Stations; LTTSs to collect the UF_6 product material; a CTPS to remove non-condensable light gases from the product stream; and a HFCVB for each LTTS that contains the valves and pipe connections from each LTTS.

~~Source material and~~ SNM is used in this area.

GI-5 Section 1.1.2.2.3 and Section 1.5

GEH states that the tails cylinder pad will have a 9000 cylinder capacity to accommodate ten years of facility operation. Based on this limit, staff will condition any license that may be issued to limit on-site storage to this limit.

Regulations in 10 CFR 70.22(a)(7) and (8) require the applicant to describe the equipment, facilities, and procedures that will be used to protect health and minimize danger to life and property.

GLE Response

GLE agrees to the condition.

License Documentation Impact

There are no changes to the license documentation as a result of this response.

GI-6 Section 1.1.4.1 and Table 1-1

State if mixed Resource Conservation and Recovery Act hazardous and low-level radioactive wastes are expected to be generated, provide an estimate of the volume of waste expected, and state how these wastes will be managed. State if all low-level radioactive wastes are expected to be Class A.

Regulations in 10 CFR 70.22(a)(7) and (8) require the applicant to describe the equipment, facilities, and procedures that will be used to protect health and minimize danger to life and property.

GLE Response

GLE does not intend to generate mixed wastes. Low-level radioactive waste is expected to be Class A waste.

License Documentation Impact

Section 1.1.4.1 will be revised as follows:

"Operation of the GLE Commercial Facility generates refuse and other nonhazardous solid waste, wastes designated as RCRA hazardous wastes, and LLRWs. No high-level radioactive wastes are generated by GLE Commercial Facility operations. GLE does not intend to generate mixed wastes. Low-level waste is expected to be Class A waste. The types, sources, and estimated quantities of solid wastes generated by GLE Commercial Facility operations are summarized in Table 1-1, Typical Types, Sources, Quantities of Solid Wastes Generated by GLE Commercial Facility Operations*, and Table 1-2,* Management of Solid Wastes*."*

GI-7 Section 1.1.4.2 and Section 1.1.6

State where and for what liquid waste streams analyses will be made to ensure that liquid effluents meet the release requirements in 10 CFR Part 20 and National Pollution Discharge Elimination System (NPDES) release requirements. State if the effluents from the Radioactive Liquid Effluent Treatment System are monitored to demonstrate compliance with 10 CFR Part 20 liquid effluent release limits before releasing them to the Final Process Lagoon Treatment Facility. State what monitoring will be performed on gaseous effluents to meet 10 CFR Part 20 and the U.S. Environmental Protection Agency National Emission Standards for Hazardous Air Pollutants (NESHAPS) airborne release limits.

Sections 1.1.4.2 and 1.1.6 provide brief discussions of liquid and gaseous waste streams that will be generated at the facility, but do not mention how and where it will be demonstrated that the release limits in 10 CFR Part 20, NPDES, and NESHAPS standards will be met.

Regulations in 10 CFR 70.22(a)(7) and (8) require the applicant to describe the equipment, facilities, and procedures that will be used to protect health and minimize danger to life and property.

GLE Response

The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area will not exceed the values specified in table 2 of appendix B to part 20.

For uranium isotopes present in commercial grade uranium hexafluoride (i.e., ^{234}U, ^{235}U, and ^{238}U) the Appendix B concentration limit for water effluent is 3.0×10^{-7} μCi/cc, which is the limit to which GLE will comply. GLE intends to implement an Administrative Limit on the GLE liquid effluent treatment system as 80% of the Part 20 Appendix B concentration limit for water effluent. The liquid leaving the Radioactive Liquid Effuent Treatment System (RLETS) will be monitored to ensure that compliance with the Part 20 Appendix B limit is maintained. In addition, the liquid leaving the RLETS system will be monitored to ensure compliance with the NDPES permit levels for fluoride, as well as other constituents specified in the permit. It is anticipated that the other constituents will include total suspended solids, biological oxygen demand, oil and grease, total nitrogen, dissolved oxygen, and pH.

GLE will comply with the Part 20 Appendix B uranium concentration limit for air effluents. GLE intends to implement an Administrative Limit on air effluents as 80% of the Part 20 Appendix B concentration limit for air effluents. Air effluents will be monitored at the facility stack to ensure that compliance with 10 CFR Part 20 Appendix B value for uranium is not exceeded. The stack will be sampled continuously to measure radioactivity of the exhaust air. The collection filter in the sample system will be removed on a daily schedule during initial operation and analyzed for gross alpha activity. The periodicity of sampling will eventually decrease to weekly if the results are shown to be continually low during normal operations.

The U.S. Environmental Protection Agency (EPA) develops and promulgates national air emission standards to limit the amount of specific air toxic compounds designated by EPA as Hazardous Air Pollutants (HAPs) that are released from specific categories of stationary sources. These standards are called the National Emission Standards for Hazardous Air Pollutants (NESHAP). Uranium enrichment processes are not a source category subject to a NESHAP. However, there is a NESHAP is applicable to certain types of industrial cooling towers. The cooling towers planned for use with the GLE Facility will not be subject to this NESHAP because the cooling towers do not meet the rule applicability criteria.

The North Carolina Air Quality Division (NC DAQ) will establish in a site-specific air permit the emissions limits, operating conditions, monitoring requirements and other requirements for non-radioactive air emissions (both criteria air pollutant and air toxics) released from the Proposed GLE Facility. The State of North Carolina's air toxic regulations are implemented as a site-specific, public health risk-based program that is separate from the federal NESHAP program. For individual toxic air pollutants (TAPs), the NC DAQ establishes a specific ambient concentration level, referred to as the acceptable ambient level (AAL), above which the substance may be considered to have an adverse effect on human health. The NC DAQ has developed AALs for 97 TAPs. These AALs are used by the NC DAQ for air permitting of a new or modified facility on a case-by-case basis to set maximum emissions limits for specific TAPs from sources at the affected facility so that the applicable AALs are not exceeded at the facility property boundary (i.e., fenceline).

GLE will comply with all air emissions limits, facility operating conditions, and air emissions monitoring requirements specified by the air permit issued by the NC DAQ for the Proposed GLE Facility. A final air permit has not yet been issued by the NC DAQ for the Proposed GLE Facility. For the non-radioactive air emission sources at the Proposed GLE Facility, preliminary discussions with NC DAQ indicate that NC DAQ will issue GLE an air permit designating the Proposed GLE Facility as a synthetic minor source. It is anticipated that the air permit conditions will include monitoring fluoride emissions from the Proposed GLE Facility main building stack to demonstrate compliance with the expected site-specific emission permit limits that will be established by the NC DAQ. Also, the air permit will include permit conditions for the stationary sources of criteria air pollutant emissions operated in association with the uranium enrichment operations, such as the type of fuel to be burned in the auxiliary diesel generator units and the maximum number of hours that these generators may operate in a year.

License Documentation Impact

Sections 1.1.6.1 and 1.1.6.2 will be revised as follows:

"1.1.6.1 Process Wastewaters

Uranium enrichment operations performed inside the Operations Building generate process wastewater from decontamination, cleaning wash water, and laboratory wastes. The waste streams contain small concentrations of uranium and are collectively referred herein as liquid radioactive waste. Liquid radioactive waste is treated to remove uranium and fluoride as described in Section 1.1.4, *Waste Management*.

The treated wastewaters from the RLETS are discharged to the existing Wilmington Site FPLTF. This facility currently receives Wilmington Site process wastewater, including the treated effluent from the GNF-A FMO Facility Radiological Waste Treatment System. The treated effluent from the FPLTF is discharged via NPDES-permitted Outfall 001 to the Wilmington Site effluent channel where it is combined with stormwater, discharging groundwater, and treated sanitary wastewater effluent. The effluent channel flows to the unnamed Tributary No. 1 to the Northeast Cape Fear River. The liquid leaving the Radioactive Liquid Effuent Treatment System (RLETS) will be monitored to ensure compliance with the Part 20 Appendix B limit. In addition, the liquid leaving the RLETS system will be monitored to ensure compliance with the NDPES permit levels for fluoride, as well as other constituents specified in the permit. It is anticipated that the other constituents will include total suspended solids, biological oxygen demand, oil and grease, total nitrogen, dissolved oxygen, and pH."

1.1.6.2 Air Effluents

The laser-based enrichment process is a closed process with no vents needed for routine venting of process gases. Some short-term gaseous releases occur inside the Operations Building during activities associated with operations such as the connection/ disconnection of UF_6 cylinders to process equipment and process equipment maintenance activities. These gaseous releases are routed through the building's ventilation system. The ventilation system air stream passes through a series of emissions-control devices consisting of high-efficiency particulate air (HEPA) filters and high-efficiency gas absorption (HEGA) filters. The exhaust air stream from these emission controls is vented to the atmosphere and monitored for uranium and fluoride. Table 1-5, *Typical GLE Air Emissions*, shows the typical air effluent concentrations from the Operations Building and the required regulatory limits. GLE will comply with the requirements in 10 CFR Part 20 Appendix B for uranium air effluents, and with the requirements specified in the North Carolina Department of Air Quality permit for monitoring of fluorides (as well as other operational controls/conditions specified in the permit)."

GI-8 Section 1.1.7

Provide data on the expected levels of trace impurities or contaminants in feed and product materials or provide references to specific American Society of Testing and Materials standards for feed and product materials.

Regulations in 10 CFR 70.22(a)(7) and (8) require the applicant to describe the equipment, facilities, and procedures that will be used to protect health and minimize danger to life and property. Guidance in NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Section 1.1.4.3(4), requests information on trace impurities and contaminants in materials used and produced by the facility.

<u>GLE Response</u>

*GLE intends to utilize Commercial Natural UF_6 feed stock meeting the requirements of ASTM C 787-06, "*Standard Specification for Uranium Hexafluoride for Enrichment*". At this time, GLE does not intend to use "Reprocessed UF_6" as feed stock, and consistent* *with ASTM C 787-06, GLE will require that suppliers possessing feed cylinders contaminated with Reprocessed UF_6 feed stock provide additional evidence of uranium purity that will be backed up by statistical sampling of feed stock at GLE. As such, impurities in the feed are expected to be consistent with, or less than, those quantities specified in this standard. GLE intends to produce enriched uranium meeting the requirements of ASTM C 996-04, "*Standard Specification for Uranium Hexafluoride Enriched to Less than 5 % ^{235}U", *for Enriched Commercial Grade UF_6 and any additional customer specifications.*

License Documentation Impact

GLE will add the following paragraph to Section 1.1.7:

"GLE will utilize Commercial Natural UF_6 feed stock meeting the requirements of ASTM C 787-06, *Standard Specification for Uranium Hexafluoride for Enrichment*. At this time, GLE does not intend to use "Reprocessed UF_6" as feed stock, and consistent with ASTM C 787-06, GLE will require that suppliers possessing feed cylinders contaminated with Reprocessed UF_6 feed stock provide additional evidence of uranium purity that will be backed up by statistical sampling of feed stock at GLE. As such, impurities in the feed are expected to be consistent with, or less than, those quantities specified in this standard. GLE will produce enriched uranium meeting the requirements of ASTM C 996-04, *Standard Specification for Uranium Hexafluoride Enriched to Less than 5 % ^{235}U*, for Enriched Commercial Grade UF_6 and any additional customer specifications."

Also, GLE will add the following line item to Table 1-7:

^{99}Tc, transuranic isotopes and other contamination	Any	Amount that exists as contamination as a consequence of historical feed of recycled uranium at other facilities.

GI-9 Section 1.2.1.2

Provide the States in which GEH Nuclear Energy Holdings and General Electric (GE) Company are chartered. Information in Section 1.2.1.2 contains the name of the State in which parents of GEH are chartered. However, the name of the State in which these corporations are chartered was not provided.

Regulations in 10 CFR 40.31 and 10 CFR 70.32 require that each application for a license include information on the identity of the applicant.

GLE Response

GEH Nuclear Energy Holdings is a Delaware Limited Liability Company and General Electric (GE) Company is a corporation organized under the laws of the State of New York.

License Documentation Impact

License Application Chapter 1, Section 1.2.1.2, second sentence will be revised as follows:

"Holdings, a Delaware limited liability company, is a subsidiary of majority owner GENE Holding LLC (GENE), which is a Delaware limited liability company wholly owned by General Electric Company (GE), a U.S. corporation organized under the laws of the State of New York, and of minority owner Hitachi America, Ltd., which is a wholly owned subsidiary of Hitachi Ltd., a Japanese corporation."

GI-10 Section 1.2.2.1

Provide more detail describing the construction phases to include identifying the facilities and equipment that will be needed for each specific, planned construction phase. In the Integrated Safety Analysis (ISA) Summary, include any accident sequences that may be created because of ongoing construction activities that take place concurrently with operations.

The licensing basis documents, as currently written, describe a facility assuming that full operation will begin at the completion of construction. The licensing basis documents need to specifically define the facilities and equipment, applicable to the individual construction phases, so that the U.S. Nuclear Regulatory Commission (NRC) can verify that construction has been performed in accordance with the license.

Under 10 CFR 40.41(g) and 70.32(k), NRC must conduct a construction inspection before operations can begin to ensure that the facility has been constructed in accordance with the license.

The regulations in 10 CFR 70.65(b)(4) require the ISA Summary to contain information that demonstrate compliance with the requirements in 10 CFR 70.61 and 70.64.

GLE Response

The phases of construction include Early Construction, Construction to Ramp up to 6 MSWU, Operation at 6 MSWU. The facility described in the License Application assumes that the facility is operating at 6MSWU. In reality, during the ramp up phase, the facility will be operating at approximately 1 MSWU during year 1, 2 MSWU during year 2, 3 MSWU during year 3, 4 MSWU during year 4, 5 MSWU during year 5, and 6 MSWU during year 6 and every year thereafter. The initial construction plan includes building the Operations Building in its entirety, and equipping it with the necessary equipment to generate 1 MSWU. During year one, while the facility is operating at 1 MSWU, equipment/component installation will be occurring simultaneously.

The accident analysis that was prepared for the License Application was intended to be conservative by assuming a 6 MSWU plant. However that analysis did not include potential accidents from ongoing construction activities that take place concurrently with operations because detailed design, operation, and schedule information is necessary to perform that analysis. GLE commits revising the ISA Summary to include any accident sequences that may be created because of ongoing construction activities that take place concurrently with operations. This revised ISA Summary will be submitted to the

NRC 6 months prior to receipt of SNM in order for the NRC to review the analyses. GLE expects the NRC to impose a License Condition to document this commitment. It is worth noting that the current accident analyses did include general industrial safety accidents causing releases of SNM, therefore, GLE does not believe that the accident analyses to be performed will differ greatly from what is currently presented.

Licensing Documentation Impact

There are no changes to the license documentation as a result of this response.

GI-11 Section 1.2.2.2

Provide the proposed financial plan for the construction and operation of the facility (i.e., if known, the proposed actual percentages of debt and equity to be used in the financing of the project, and a brief statement on any long-term contracts or commitments in place or under negotiation).

Section 1.2.2.2 provides general project funding commitments, but does not include current detailed financial plan information.

The regulations in 10 CFR 70.22(a)(8) require financial qualifications of the applicant, "Where the nature of the proposed activities is such as to require consideration of the applicant's financial qualifications to engage in the proposed activities in accordance with the regulations in this chapter, the Commission may request the applicant to submit information with respect to his financial qualifications."

GLE Response

GLE will use both debt and equity financing (ratios yet to be determined) to fund each phase of the project. In addition, GLE is pursuing long-term contracts with potential customers.

License Documentation Impact

There are no changes to the license documentation as a result of this response.

GI-12 Section 1.2.2.4

American Nuclear Insurers (ANI) currently provides $200 million in coverage for the GE fuel fabrication facility. We understand that this insurance policy of $200 million is all inclusive and covers the entire GE site encompassing both the fuel fabrication facility and the proposed uranium enrichment facility, which are on the same site. The existing GE fuel fabrication facility insurance is sufficient to fulfill NRC regulations. Provide written confirmation of the existing ANI issued insurance policy and its applicability to the proposed uranium enrichment facility for the staff to complete its review.

Section 1.2.2.4 states that nuclear liability insurance will take effect upon the receipt at the GEH facility of source material or SNM. Until such time, GEH will rely on the liability coverage of its parent companies assuming this liability is not to exceed $1 million during the construction period. Self-insurance of standard liability is a standing policy for the three parent organizations, and give the limited materiality ($1M), GEH will utilize the parent organization as back-stops if necessary in lieu of a specific insurance policy.

The regulations in 10 CFR 140.13(b) state that each holder of a license issued under Parts 40 or 70 of this chapter for a uranium enrichment facility that involves the use of source material or special nuclear material is required to have and maintain liability insurance. The liability insurance must be the type and in the amounts the Commission considers appropriate to cover liability claims arising out of any occurrence within the United States (US) that causes, within or outside the US, bodily injury, sickness, disease, death, loss of or damage to property, or loss of use of property arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of chemical compounds containing source material or special nuclear material. Proof of liability insurance must be filed with the Commission as required by 10 CFR 140.15 before issuance of a license for a uranium enrichment facility under parts 40 and 70 of this chapter.

GLE Response

GLE intends to have and maintain up to $300 million to satisfy the 10 CFR 140.13b requirement prior to receipt of licensed material. The current coverage for the GE Site is considered adequate until the facility is ready to begin operations. At that time, GLE will increase the amount to approximately $300 million.

Because full liability insurance coverage will not be provided until prior to receipt of licensed material, GLE expects the NRC to impose the following license condition:

> "The licensee shall provide proof of full liability insurance as required under 10 CFR 140.13b, at least 30 days prior to the planned date for obtaining licensed material. If the licensee is proposing to provide less than $300 million of liability insurance coverage, the licensee shall provide, to the NRC for review and approval, an evaluation supporting liability insurance coverage in amounts less than $300 million at least 120 days prior to the planned date for obtaining licensed material."

License Documentation Impact

The last paragraph of Section 1.2.2.4 of the license application will be revised as follows:

"The aforementioned insurance will take effect upon the receipt at the GLE Commercial Facility of source material or SNM. Until such time, GLE will rely on the current GE Site insurance policy for coverage."

GI-13 Section 1.2.3

Provide information on any technium-99 (Tc-99) and transuranics that might be possessed as a result of feed, product, or tails cylinders that may have been contaminated by historical use of recycled materials at other facilities and provide materials specifications for feed and product materials to ensure that contamination levels are met.

The regulations in 10 CFR 30.32 and 10 CFR 40.31 require each application for a license to include the name, chemical and physical form, and maximum amount of licensed material that will be possessed.

GLE Response

As provided in response to RAI GI-8, GLE intends to utilize Commercial Natural UF_6 feed stock meeting the requirements of ASTM C 787-06, Standard Specification for Uranium Hexafluoride for Enrichment. At this time, GLE does not intend to use "Reprocessed UF_6" as feed stock, and consistent with ASTM C 787-06, GLE will require that suppliers possessing feed cylinders contaminated with Reprocessed UF_6 feed stock provide additional evidence of uranium purity that will be backed up by statistical sampling of feed stock at GLE. As such, impurities in the feed are expected to be consistent with, or less than, those quantities specified in this standard. GLE intends to produce enriched uranium meeting the requirements of ASTM C 996-04, Standard Specification for Uranium Hexafluoride Enriched to Less than 5 % ^{235}U, for Enriched Commercial Grade UF_6 and any additional customer specifications.

Licensing Documentation Impact

GLE will add the following paragraph to Section 1.2.3:

"GLE intends to utilize Commercial Natural UF_6 feed stock meeting the requirements of ASTM C 787-06, *Standard Specification for Uranium Hexafluoride for Enrichment*. At this time, GLE does not intend to use "Reprocessed UF_6" as feed stock, and consistent with ASTM C 787-06, GLE will require that suppliers possessing feed cylinders contaminated with Reprocessed UF_6 feed stock provide additional evidence of uranium purity that will be backed up by statistical sampling of feed stock at GLE. As such, GLE expects to possess only trace amounts of other radionuclides consistent with the natural decay of uranium."

Also, GLE will add the following line item to Table 1-7:

^{99}Tc, transuranic isotopes and other contamination	Any	Amount that exists as contamination as a consequence of historical feed of recycled uranium at other facilities.

GI-14 Section 1.2.5.3

Provide clarification on the commitment to provide full financial assurance for facility decommissioning at start-up.

In Section 1.2.5.3, GEH indicated that it would provide full financial assurance for facility decommissioning at start-up, but did not specifically state if start-up refers to the time that the licensee would take possession of licensed material. Because decommissioning obligation would begin at the time the licensee takes possession of licensed material, final, executed decommissioning financial assurance instruments need to be provided prior to taking possession of licensed material. In addition, the applicant needs to clarify if full financial assurance for facility decommissioning refers to the full 6-million Separative Work Unit capacity of the facility.

Under 10 CFR 40.36 and 10 CFR 70.25, an applicant for a uranium enrichment facility must provide a decommissioning funding plan for providing financial assurance for decommissioning.

GLE Response

Startup refers to the time that GLE will receive licensed material. Full financial assurance for the facility will be provided assuming a 6 MSWU facility.

License Documentation Impact

Section 1.2.5.3, the fourth paragraph will be revised as follows:

"Finally, providing financial assurance for UF_6 tails disposition on an incremental basis is justified in view of GLE's commitments to: (1) provide full financial assurance for facility decommissioning (assuming a 6 MSWU facility) at startup (startup refers to when GLE receives licensed material); (2) update its UF_6 tails dispositioning cost estimate annually, on a forward-looking basis, to ensure that the financial assurance reflects the current projected inventory of UF_6 tails at the facility (including any previously-generated tails still requiring disposition); and (3) adjust other decommissioning costs periodically, and no less frequently than every three years. This approach will allow GLE to consider available operating experience and other relevant information, including actual UF_6 tails inventory values and generation rates, and to ensure that sufficient decommissioning financial assurance is available at any point during the licensed operating life of the facility."

GI-15 Section 1.3.1.2; Integrated Safety Analysis Summary Sections 2.1.2 and 2.5.2

Provide the flood-level estimate corresponding to a flood hazard with an annual probability of 10^{-4} for the facility site. Either show that the facility is designed to withstand a flood with an annual probability equal to or smaller than 10^{-4}, or show that the consequences of the flood-induced accident sequence satisfy requirements in 10 CFR 70.61(c).

The applicant excluded flooding as a potential external hazard from further consideration for facility design and from the integrated safety analysis (ISA) for the proposed facility because the proposed facility will be located above the 100- and 500-year flood plains for the region. ISA Summary Table 4.16-1 indicates that natural phenomena causing facility flooding may have intermediate consequences. Consequently, the applicant should either demonstrate that the flood-induced accident event is unlikely (the applicant defines "unlikely" as an event with an annual probability between 1.0×10^{-4} and 1.0×10^{-5}) or that the consequences are within the limits stipulated in 10 CFR 70.61(c). Using the basis that the proposed facility is above the 500-year flood plain alone is not sufficient to exclude the potential flood hazard, because the 500-year flood is a likely, not an unlikely, event based on the applicant's definition.

The regulations in 10 CFR 70.64(a)(2) require the applicant to include adequate protection against natural phenomena in its design of the facility, and 10 CFR

70.62(c)(iv) requires the applicant to conduct and maintain an integrated safety analysis (ISA) that identifies potential accident sequences caused by credible external events. In addition, 10 CFR 70.61(c) requires the applicant to demonstrate an intermediate consequence accident event is either unlikely or its consequences are within acceptable limits.

GLE Response

GLE will submit a response to this question by January 29, 2010.

GI-16 Section 1.3.3.3.2 and ISA Summary Section 2.5.7.1

Show that the facility is designed to withstand snow loads from snowfall events with an annual probability of 10^{-5} or smaller or show that the consequences of the snow-load-induced event satisfies 10 CFR 70.61(c).

ISA Summary Table 4.16-1 indicates that snow buildup on the facility roof may have high consequences. The applicant considered the snow-load-induced accident event by including a design basis ground snow load of 1.2 kiloPascals (kPa) (25 pounds per square foot (psf)) for the proposed facility. The applicant suggested that this design basis is sufficient to make the snow-load-induced accident event highly unlikely because the historical ground snow load (0.38 kPa (8 psf)) is substantially smaller than the design basis to be used for the facility design. However, the applicant does not show whether the historical ground snow load corresponds to the 1.0×10^{-5}/year ground snow load. Because the applicant did not characterize the ground snow load with an annual probability of 1.0×10^{-5}, the NRC staff cannot determine whether the design basis ground snow load the applicant proposed is sufficient to make the ground snow-loadinduced accident event highly unlikely.

The regulations in 10 CFR 70.64(a)(2) require the applicant to include adequate protection against natural phenomena in its design of the facility, and 10 CFR 70.62(c)(iv) requires the applicant to conduct and maintain an ISA that identifies potential accident sequences caused by credible external events. In addition, 10 CFR 70.61(b) requires the applicant to demonstrate a high consequence accident event is either highly unlikely or its consequences are within acceptable limits.

GLE Response

GLE will submit a response to this question by January 29, 2010.

GI-17 Section 1.3.3.3.7 and ISA Summary Section 2.5.5

Assess the potential hazard of a Category 5 hurricane to the proposed facility.

Section 1.3.3.3.7 indicated that a Category 5 hurricane passing within approximately 138 kilometers (km) (86 miles (mi)) of New Hanover County is a likely event with a return period of 191 to 250 years. Consequently, the likelihood of a Category 5 hurricane causing facility damage, and if necessary, the potential consequences, should be assessed and documented in the ISA Summary.

The regulations in 10 CFR 70.64(a)(2) require the applicant to include adequate protection against natural phenomena in its design of the facility, and 10 CFR 70.62(c)(iv) requires the applicant to conduct and maintain an ISA that identifies potential accident sequences caused by credible external events. In addition, 10 CFR 70.61(b) requires the applicant to demonstrate a high consequence accident event is either highly unlikely or its consequences are within acceptable limits.

GLE Response

GLE will submit a response to this question by January 29, 2010.

GI-18 Section 1.3.5.1

Provide allowable bearing pressure of soil used in the design and the method to estimate it. Also, provide design basis settlement and differential settlement values used in the structural design including the methods used to determine them. This information is needed to assess adequacy of facility design.

The regulations in 10 CFR 70.64(a)(2) require the applicant to include adequate protection against natural phenomena in its design of the facility.

GLE Response

As stated in GLE letter MFN-09-578 dated September 4, 2009, the GLE Environmental Report (submitted to the NRC on January 30, 2009) provides additional detailed information on the geophysical and geotechnical investigations performed in the GLE Study Area (Chapter 3, Section 3.3.5 and Chapter 4, Section 4.3.2 of the Environmental Report). A number of the appendices provide more information on the field and laboratory testing, and other related information (e.g., Appendix D – Information on the USGS Assessment of the Cape Fear Arch Tectonic Feature, Appendix E – Official Soil Series Descriptions for Soils within the GLE Study Area, Appendix F – Soil Test Boring Records in GLE Study Area, Appendix G – Results of the 2007 Preliminary Subsurface Investigation, Appendix H – Summary of Unified Soil Classification System, and Appendix I – Historical Earthquakes Ranked by Distance from the Wilmington Site).

The information in the above documents should provide a substantive understanding of the geophysical and geotechnical conditions of the GLE Study Area. The preliminary geophysical and geotechnical investigation performed in 2007 was for general planning purposes and used to assess the feasibility of developing this portion of the Wilmington site (the GLE Study Area). The conclusions drawn from the preliminary geophysical and geotechnical investigations are as follows:

- *The liquefaction potential of subsurface materials within the GLE Study Area was evaluated through field and laboratory tests, and the potential for these materials to liquefy and have an impact on the GLE facility is SMALL.*
- *Foundations would be designed to meet building codes and to control impacts from seismic events, as well as predicted settlement from projected building loads.*

A geotechnical design investigation to determine the structural in-ground support system necessary to support the estimated heavy loading will be completed prior to commencement of construction. The geotechnical design investigation will be performed using the applicable regulatory guidance in Regulatory Guide 1.132, Site Investigations for Foundations of Nuclear Power Plants*. When the geotechnical design investigation is completed, the NRC will be notified and the results will be available to the NRC for inspection, or they can be submitted to the NRC upon request.*

In addition, using the soil information from the geotechnical design investigation, the following activities will be conducted (the license application will be revised to incorporate these commitments):

- *The assessment of liquefaction potential of subsurface soils will be completed using the applicable guidance contained in* Regulatory Guide 1.198, Procedures and Criteria for Assessing Seismic Soil Liquefaction as Nuclear Power Plant Sites*. The Ground Motion Response Spectra used for the liquefaction analysis will be based on guidance contained in the* International Building Code*.*

- *Allowable bearing pressures for shallow and deep foundations will be evaluated using established geotechnical engineering methods.* Methods anticipated for use include those contained in the following publications: Naval Facilities Engineering Command Design Manual, NAVFAC DM 7; Foundation Engineering Handbook, H.F. Winterkorn and H.Y Fang; Foundation Analysis and Design, J. E. Bowles; and Drilled Shafts: Construction Procedures and Design Methods, Federal Highway Administration.

The evaluation of total and differential settlement for structure foundations will be completed using established geotechnical engineering methods. Methods anticipated for use include those contained in the following publications: Naval Facilities Engineering Command Design Manual, NAVFAC DM 7; Foundation Engineering Handbook, H.F. Winterkorn and H.Y Fang; and Foundation Analysis and Design, J. E. Bowles.

License Documentation Impact

The following will be added to Section 1.3.5.1 of the license application:

"Previous geotechnical investigations on the Wilmington Site found that soil conditions required the use of a specialized structural in-ground support system. A geotechnical design investigation to determine the structural in-ground support system necessary to support the estimated heavy loading will be completed prior to commencement of construction. The geotechnical design investigation will be performed using the applicable regulatory guidance in Regulatory Guide 1.132, Site Investigations for Foundations of Nuclear Power Plants."

GI-19 Section 1.3.5.3

Provide information on soil liquefaction potential at the facility site.

The applicant's LA and ISA Summary did not include information regarding soil liquefaction potential. This information is necessary to assess whether the applicant adequately considered the natural-phenomena-induced accident events.

The regulations in 10 CFR 70.64(a)(2) require the applicant to include adequate protection against natural phenomena in its design of the facility. In addition, 10 CFR 70.62(c)(iv) requires the applicant to conduct and maintain an ISA that identifies potential accident sequences caused by credible external events.

GLE Response

See the response to GI-18 above.

License Documentation Impact

The following will be added to Section 1.3.5.3 of the license application:

"Using the soil information from the geotechnical design investigation mentioned in Section 1.3.5.1, the following activities will be conducted:

- *The assessment of liquefaction potential of subsurface soils will be completed using the applicable guidance contained in* Regulatory Guide 1.198, Procedures and Criteria for Assessing Seismic Soil Liquefaction as Nuclear Power Plant Sites*. The Ground Motion Response Spectra used for the liquefaction analysis will be based on guidance contained in the* International Building Code*.*

- *Allowable bearing pressures for shallow and deep foundations will be evaluated using established geotechnical engineering methods.* Methods anticipated for use include those contained in the following publications: Naval Facilities Engineering Command Design Manual, NAVFAC DM 7; Foundation Engineering Handbook, H.F. Winterkorn and H.Y Fang; Foundation Analysis and Design, J. E. Bowles; and Drilled Shafts: Construction Procedures and Design Methods, Federal Highway Administration.

The evaluation of total and differential settlement for structure foundations will be completed using established geotechnical engineering methods. Methods anticipated for use include those contained in the following publications: Naval Facilities Engineering Command Design Manual, NAVFAC DM 7; Foundation Engineering Handbook, H.F. Winterkorn and H.Y Fang; and Foundation Analysis and Design, J. E. Bowles."

Organization and Administration (Chapter 2)

OA-1 Section 2.1.2

Provide the qualifications of the principal managers for design and construction of the facility.

This section discusses the organizational structure for the design and construction of the facility. However, qualification of the principal managers for design and construction are not provided.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of health, safety, and environment (HS&E) protection functions.

GLE Response

The principal manager qualifications are provided in the license application revision below.

License Documentation Impact

The last paragraph of Section 2.1.2 will be revised as follows:

“The qualifications of the principal managers for design and construction of the facility are as follows:

The Quality Assurance and Infrastructure Program Manager shall have, as a minimum, a bachelor’s degree in an engineering or scientific field and four years of supervisory nuclear experience in the implementation of a QA Program and at least two years experience in a QA Organization at a nuclear facility.

The Engineering Manager shall have, as a minimum, a bachelor’s degree in an engineering or scientific field and five years of related responsible experience.

The Commercial Facility Project Manager shall will have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and have a minimum of 5 years of responsible nuclear experience.

The Environmental Health and Safety Manager shall have, as a minimum, a bachelor’s degree (or equivalent) in an engineering or scientific field and five years of management experience in assignments involving regulatory activities. The manager of the GLE EHS function shall have experience in the understanding and management of NCS, Environmental Protection, and Industrial Safety programs.”

OA-2 Section 2.1.4

Provide a detailed discussion of management transitions during the proposed phased construction and simultaneous operations for multi-year periods.

In Section 1.2.2.1, GEH indicated it would perform construction in phases. However, Section 2.1.4 does not address how the management transitions will be accomplished for each phase of construction.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E protection functions.

GLE Response

Following commencement of enrichment operations of the initial phase of construction, the Facility Manager will be responsible for all site activities including continued initial construction phases. To facilitate this responsibility, the Commercial Facility Project Manager will report to the Facility Manager. Both the QA and EHS managers will retain their responsibilities and be adequately staffed to provide independent oversight for both operations and continued construction activities.

License Documentation Impact

The chapter 2 of the license application, Figure 2-2 "GLE Operations Organizational Structure During Operations" will be revised to include the Commercial Facility Project Manager and its reporting relationship.

OA-3 Section 2.2.1

Provide the qualifications for the GEH President and Chief Executive Officer (CEO).

Clarify what GEH parent company provides direction to the GEH President and CEO. As stated in Section 2.2.1, the GEH President and CEO is responsible for providing overall direction and management of GEH activities, however, no qualifications for this position are stated. In addition, GEH Nuclear Energy Fuel Cycle Senior Vice President is stated to provide overall direction to the GEH President and CEO, but there are several parent companies named General Electric-Hitachi Nuclear Energy (e.g., General Electric-Hitachi Nuclear Energy Americas and General Electric-Hitachi Nuclear Energy Holdings) and the specific parent company is not completely defined.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E protection functions.

GLE Response

The GLE President and Chief Executive Officer (CEO) qualifications will be a bachelor's degree (or equivalent) and at least 5 years relevent experience.

General Electric-Hitachi Nuclear Energy Americas is the GLE parent that provides direction to the GLE President and CEO.

License Documentation Impact

A second paragraph will be added to Section 2.2.1of the license application as follows:

"The GLE President and CEO shall have, as a minimum, a bachelor's degree (or equivalent) and at least 5 years of relevent experience."

The last sentence of the second paragraph of section 2.1.1 of the license application will be revised to read:

*"…*Chief Executive Officer (CEO) receives direction from the GLE parent company General Electric-Hitachi Nuclear Energy Americas through the GEH Fuel Cycle Senior Vice…"

OA-4 Section 2.2.3

Provide information on any stop-work authority given to the Quality Assurance (QA) Manager.

Section 2.2.3 indicates that the QA Manager has access to the Facility Manager and the authority and responsibility to contact the President and CEO regarding QA issues, but does not specifically address stop-work authority.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E protection functions.

GLE Response

The GLE QA Manager's stop-work authority will be included in the license application.

License Documentation Impact

Section 2.2.3 of the license application will be revised to include the following:

*"*The GLE QA Manager has the authority to stop work based on quality concerns. This authority to stop work and the process to resume stopped work will be included in approved procedures."

OA-5 Sections 2.2.4.1 and 2.2.7

Explain how, when the Facility Manager is absent, the Environmental, Health, and Safety (EHS) function will remain administratively independent of Operations. In Section 2.2.7, the applicant states that the EHS function is administratively independent of the operations function. In Section 2.2.7.1, the applicant states that the EHS Manager reports to the Facility Manager. In Section 2.2.4.1, the applicant states that, in the absence of the Facility Manager, the Operations Manager may assume the responsibilities and authorities of the Facility Manager. It is unclear how the EHS function will remain administratively independent under this condition.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E protection functions.

GLE Response

The last sentence in Section 2.2.4.1of the license application is unnecessary.

License Documentation Impact

The last sentence in Section 2.2.4.1 of the license will be deleted.

OA-6 Section 2.2.7.1

Provide information on the EHS Manager's independence for performing EHS audits, reviews, and control activities; independence to issue stop-work orders; and independence for approving facility changes or activities that require NRC approval.

Section 2.2.7.1 discusses the EHS Manager's responsibilities, but does not address independence for performing EHS audits, reviews, and control activities; for independence to issue stop-work orders; and approving facility changes or activities that require NRC approval.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E protection functions.

GLE Response

Additional clarification of the EHS Manager's independence will be added to the license application.

License Documentation Impact

The following paragraph will be added to Section 2.2.7.1:

"The EHS Manager works with the other facility managers to ensure consistent interpretations of EHS requirements, performs independent reviews, and supports facility and operations change control reviews. This position is independent from other management positions at the facility to ensure objective EHS audit, review, and control activities. The EHS Manager has the authority to issue "stop work" orders and must be consulted prior to resumption of stopped work. Changes to the facility or to activities of personnel that require prior NRC approval are reviewed and approved by the EHS Manager or designee."

OA-7 Section 2.2.7.5

Provide information on the qualifications of the Licensing Manager.

Section 2.2.7.5 discusses the licensing function within the Environmental, Health, and Safety Organization, but does not provide the qualifications of the Licensing Manager.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E protection functions.

GLE Response

The Licensing Manager shall have, as a minimum, five years of related experience in implementing and supervising nuclear activities in compliance with NRC regulations and facility license commitments.

License Documentation Impact

Section 2.2.7.5 will be revised as follows:

"2.2.7.5 Licensing Function

The Licensing function reports to the GLE EHS Manager and has responsibility for coordinating facility activities to ensure compliance with applicable NRC requirements. The Licensing function is also responsible for ensuring abnormal events are reported to the NRC in accordance with NRC regulations.

The Licensing Manager shall have, as a minimum, five years of related experience in implementing and supervising nuclear activities in compliance with NRC regulations and facility license commitments."

OA-8 Section 2.2.7.6

Provide information on the organization responsible for ensuring laser safety.

Section 2.2.7.6 describes the responsibilities of the Industrial Safety Manager, but does not discuss the responsibilities for ensuring laser safety.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E protection functions.

GLE Response

The responsibility for laser safety will be added to the Industrial Safety Manager's position.

License Documentation Impact

Another bullet will be added to Section 2.2.7.6 of the license application:

- *Ensure proper implementation of the Laser Safety Program*

OA-9 Section 2.2.7.8

Provide information on the responsibilities of the Radiation Protection Manager related to training personnel in radiation protection policy and practices.

Section 2.2.7.8 describes the responsibilities of the Radiation Protection Manager, but does not discuss the responsibilities for training personnel in radiation protection policy and practices.

The regulations in 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E protection functions.

GLE Response

The Radiation Protection Manager is responsible for overseeing the training program for training personnel in radiation protection policy and practices.

Licensing Documentation Impact

Section 2.2.7.8 shall be revised as follows:

"***2.2.7.8 Radiation Protection Function***

The RP function is administratively independent of Operations and has the authority to shutdown potentially unsafe operations. The RP Manager is responsible for overseeing the training program for training personnel in radiation protection policy and practices. The RP Manager establishes the initial training program, and as stated in Section 4.5.5, reviews the contents of the training program bi-annually. The RP Manager must approve restart of any operation shutdown by the RP function. Designated responsibilities for the RP Manager typically include, but are not limited to, the following:

- Establish and maintain the RP Programs, procedures, and training;
- Evaluate radiation exposures of employees and visitors, and ensure the maintenance of related records;
- Conduct radiation and contamination monitoring and control programs;
- Evaluate the integrity and reliability of radiation detection instruments;
- Provide RP support for ISAs and configuration control;
- Provide advice and counsel to area managers on matters of RP;
- Support emergency response planning; and
- Assess the effectiveness of the RP Program through audit programs.

The RP Manager shall have, as a minimum, a bachelor's degree in an engineering or scientific field, three years of experience that includes assignments involving responsibility for RP, and experience in the understanding, application, and direction of RP Programs.

A senior engineer of the RP function shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and two years of nuclear industry experience in the assigned function. Alternate minimum experience qualification for a senior member of the RP function is a professional certification in health physics. A senior member shall have experience in the assigned safety function, and has authority and responsibility to conduct activities assigned to the RP function."

Integrated Safety Analysis (Chapter 3)

ISA-1 General

Provide a listing of applicable codes and standards, and any exceptions taken, in the license application.

A commitment to the use of codes and standards is needed to ensure that equipment will be designed to meet appropriate safety requirements. Since the ISA Summary is not a part of the application, commitments to the use of codes and standards is needed in the license application.

Regulations in 10 CFR 70.22(a)(7) and (8) require the applicant to describe the equipment, facilities, and procedures that will be used to protect health and minimize danger to life and property.

GLE Response

GLE commits to follow the industry practice to adhere to all "shall" statements in standards applied. Suggestions and recommendations in applied standards (so called "should" statements) will not be considered by GLE as binding commitments unless it is specifically stated that GLE's intent is to treat the "should" statements as binding commitments (i.e., treat as if they are "shall" statements). GLE may make such commitments as part of the description of the safety program basis. If a definitive commitment to a "should" statement is necessary to provide adequate protection, GLE may provide explanation of this as an issue in response to requests for additional information (RAI) on specific licensing actions. Suggestions and recommendations in applied standards may or may not be used by GLE, at its discretion if not otherwise identified as binding commitments.

Shown below is an inclusive listing of Codes and Standards that are planned to be used in the safe design of the facility.

GLE Facility Design Code and Standards[1]			
Code Group / Reference	**Code Number**	**Year or Edition**	**Title**
ACGIH		2007	*Industrial Ventilation: A Manual of Recommended Practice*
ACI	117	1990	*Standard Tolerance for Concrete Construction*
ACI	318	2008	*Building Code Requirements for Structural Concrete*
ACI	349	2007	*Code Requirements for Nuclear Safety Related Concrete Structures*
AICHE		2005	*Guidelines for Hazard Evaluation Procedures, 2nd Edition,* 2005
AIHA		1988	American Industrial Hygiene Association, *Emergency Response Planning Guidelines*, AIHA Emergency Response Planning Guideline committee, Akron, OH, 1988
AISC	325-05 Thirteenth edition	2006	*Manual of Steel Construction*

[1] In citing industry consensus codes and standards the applicant has not delineated specific commitments in the standards that will be adopted. These industry consensus codes and standards may not be adopted in their entirety, but form the initial baseline of applicable codes and standards that are evaluated during the design of the GLE CF. Actual codes and standards are established in design documents and the design criteria manual. These documents provide the level of compliance or non-compliance necessary to understand the design criteria used for the design and construction of the GLE Facilities.

GLE Facility Design Code and Standards[1]			
Code Group / Reference	Code Number	Year or Edition	Title
AISC	341	2005	*Seismic Provision for Structural Steel Buildings*
AISC	360	2005	*Specification for Structural Steel Building*
AISC	M-011	1989	*Manual of Steel Construction Allowable Stress, Ninth Edition*
AISC	N-690 (S327)	2006	*Nuclear Facilities, Steel Safety-Related Structures for Design and Fabrication*
ANSI	N14.1	2001	ANSI N14.1-2001, N*uclear Materials - Uranium Hexafluoride - Packaging for Transport*, American National Standards Institute, 2001
ANSI/AIHA	Z9.5	2003	*Laboratory Ventilation*
ANSI/ANS	2.26	2004	ANSI/ANS-2.26-2004: *Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design*
ANSI/ANS	8.1	2007	ANSI/ANS 8.1-1998 (R2007), *Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactor*", 2007
ANSI/ANS	8.3	1997	ANSI/ANS 8.3 1997, *Criticality Accident Alarm System* (ANSI, 1997) as modified by Regulatory Guide 3.71, Nuclear Criticality Safety Standards Fuels and Material Facilities (NRC, 1998), (R 2003)
ANSI / ASME	AG-1	2003	ANSI/ASME AG-1, *Code on Nuclear Air and Gas Treatment*, ASME International, 2003, Section *FC-5160*.
ANSI/ASME	B16.5	1996	*Pipe Flanges and Flanged Fittings*
ANSI/ASME	B30.2	2005	*Overhead and Gantry Cranes (Top Running Bridge, Single or Multiple Girder, Top Running Trough Hoist)*
ANSI/ASME	B31.3	2006	ASME B31.3, *Process Piping*, 2006 (excludes Vacuum Piping Systems)
ANSI/ASME	B31.9	2008	ANSI/ASME B31.9, *Building Services Piping*, 2008
ANSI/ASME	NOG-1	2004	*Rules for Construction of Overhead and Gantry Cranes (Top Running Bridge, Multiple Girder)*
ANSI/ASSE	Z117.1	2003	American National Standards Institute (ANSI)/American Society of Safety Engineers (ASSE), 2003, *Safety Requirements for Confined Spaces*, Z117.1-2003
ANSI/IEEE	C2	2007	*National Electric Safety Code*
ANSI/IEEE	C37.04	2006	IEEE C37.04, *Rating Structure for AC High-Voltage Circuit Breakers Rated on a Symmetrical Current Basis* - 2006
ANSI/IEEE	C37.06	2000	IEEE C37.06, *Switchgear - AC High-voltage Circuit Breakers Rated on a Symmetrical Current Basis - Preferred Ratings and Related Required Capabilities* - 2000
ANSI/IEEE	C37.11	2003	IEEE C37.11, *AC High-Voltage Circuit Breaker Control Requirements* - 2003
ANSI/IEEE	C37.20.2	2005	IEEE C37.20.2, *Metal-Clad Switchgear* - 2005
ANSI/IEEE	C37.90	2005	IEEE C37.90, *Standard for Relays and Relay Systems Associated with Electric Power Apparatus* - 2005

GLE Facility Design Code and Standards[1]			
Code Group / Reference	Code Number	Year or Edition	Title
ANSI/IEEE	C37.100	2001	IEEE C37.100, *Definitions for Power Switchgear* - 2001
ANSI/IEEE	C57.12.80	2002	IEE C57.12.80, *Standard Terminology for Power and Distribution Transformers* - 2002
ANSI/IEEE	C57.12.90	2006	IEEE C57.12.90, *Standard Test Code for Liquid-Immersed Distribution, Power, and Regulating Transformers* - 2006
ANSI/IEEE	C57.12.91	2001	IEEE C57.12.91, *Standard Test Code for Dry-Type Distribution and Power Transformers* - 2001
ANSI/IEEE	STD 500	1984	IE Std 500-1984, *IEEE Guide to the Collection and Presentation of Electrical, Electronic, Sensing Component, and Mechanical Equipment Reliability Data for Nuclear-Power Generating Stations*
ANSI/ISA	67.04.01	2000	*ANSI/ISA* 67.04.01-2000, *Setpoints for Nuclear Safety-Related Instrumentation*, 2000
ASCE	7-05	2006	*ASCE 7-05, Minimum Design Loads for Buildings and Other Structures,* American Society of Civil Engineers, January 2006
ASHRAE	62	2001	ASHRAE 62, V*entilation for Acceptable Indoor Air Quality*, 2001
ASHRAE	62.1	2001	ASHRAE 62, V*entilation for Acceptable Indoor Air Quality*, 2001
ASHRAE	90.1	2001	ASHRAE 90.1, *Energy Standard for Buildings Except Low-Rise Residential Buildings*, 2001
ASHRAE	90A	1980	The American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) Standard 90A, *Energy Conservation in New Building Design*, 1980
ASME	N510	2007	Testing of Nuclear Air Treatment Systems, 2007
ASME	NQA-1	1994	ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications, W/Addenda Part I: Basic Requirements and Supplementary Requirements for Nuclear Facilities, Part II: Quality Assurance Requirements for Nuclear Facility Application, Part III: Nonmandatory Appendices*
ASME	Section VIII	2007	ASME, Boiler and Pressure Vessel Code
ASTM	C761-04		ASTM C761-04 – *Standard Test Methods for Chemical, Mass Spectrometric, Spectrochemical, Nuclear, and Radiochemical Analysis of Uranium Hexafluoride*, 2004
ASTM	C787-06	2006	ASTM C787-06, *Standard Specification for Uranium Hexafluoride for Enrichment*, ASTM International, 2006
ASTM	C996-04	2004	ASTM C996-04, *Standard Specifications for Uranium Hexafluoride Enriched to Less than 5%* ^{235}U, ASTM International, 2004

GLE Facility Design Code and Standards[1]			
Code Group / Reference	**Code Number**	**Year or Edition**	**Title**
ASTM	D6646-03	2003	ASTM D6646-03, *Standard Test Method for Determination of the Accelerated Hydrogen Sulfide Breakthrough Capacity of Granular and Pelletized Activated Carbon*, 2003
ASTM	E84	2008	*Standard Test Method for Surface Burning Characteristics of Building Materials*
ASTM	E814	2008	ASTM E814, B, *Standard Test Method for Fire Tests of Penetration Firestop Systems,* 2008.
CGA	G-5		Compressed Gas Association, CGA G-5, *Hydrogen*
CGA	H-5		Compressed Gas Association (CGA) H-5 *Installation Standards for Bulk Hydrogen Supply Systems*
CGA	P-1		Compressed Gas Association, CGA P-1, *Safe Handling of Compressed Gas in Cylinders*
CGA	SB-2	2001	Compressed Gas Association, Inc., 2001, Safety Bulletin, *Oxygen-Deficient Atmospheres*, SB-2, 4th edition
IAEA	TS-R-1	2005	IAEA Safety Requirements No. TS-R-1, *Regulations for the Safe Transport of Radioactive Material,* 2005
ICC	NCBC	2009	2006 ICC *International Plumbing Code, IPC* w/2009 NC Amendments
ICC	NCBC	2009	2006 ICC *International Mechanical Code, IMC* w/2009 NC Amendments
ICC	NCBC	2009	North Carolina State Building Codes, Version 1.0, 2009 2006 ICC International Building Code w/2009 NC Amendments
ICC	NCFC	2009	North Carolina Fire Code, IFC - 2006 w/2009 NC Amendments
IEEE	80	2000	*Guide for Safety in AC Substation Grounding*
IEEE	81	1983	*Guide for Measuring Earth Resistivity, Ground Impendence and Earth Surface Potential of a Ground System*
IEEE	142	2007	*Grounding of Industrial and Commercial Power Stations*
IEEE	383	2003	*IEEE Standard for Qualifying Electric Cables and Field Splices for Nuclear Generating Systems*
IEEE	519	1992	*Recommended Practices and Requirements for Harmonic Control in Electrical Power Systems*
IEEE	1202	2006	*IEEE Standard for Flame Testing of Cables For Use in Cable Tray in Industrial and Commercial Occupancies*
NEMA	SG 4	2005	NEMA SG 4, *Alternating - Current High-Voltage Circuit Breaker* - 2005
NFPA	1	2009	NFPA 1, *Fire Code*, National Fire Protection Association, 2009
NFPA	10	2002	NFPA 10, *Standard for Portable Fire Extinguishers*, National Fire Protection Association, 2007
NFPA	13	2007	NFPA 13, *Installation of Sprinkler Systems*, National Fire Protection Association, 2007

GLE Facility Design Code and Standards[1]			
Code Group / Reference	**Code Number**	**Year or Edition**	**Title**
NFPA	14	2007	NFPA 14, *Standard for the Installation of Standpipes and Hose Systems*, National Fire Protection Association, 2007
NFPA	20	2007	NFPA 20, *Standard for the Installation of Stationary Fire Pumps for Fire Protection*, National Fire Protection Association, 2007
NFPA	22	2008	NFPA 22, *Standard for Water Tanks for Privative Fire Protection*, National Fire Protection Association, 2008 Edition
NFPA	24	2007	NFPA 24, *Standard for the Installation of Private Fire Service Mains and Their Appurtenances, National Fire Protection Association,* 2007
NFPA	25	2008	NFPA 25, *Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, National Fire Protection Association, 2008
NFPA	30	2008	NFPA 30, *Flammable and Combustible Liquids Code*, National Fire Protection Association, 2008
NFPA	45	2004	NFPA 45, *Standard on Fire Protection for Laboratories Using Chemicals*, National Fire Protection Association, 2004
NFPA	51	2007	NFPA 51, *Design and Installation of Oxygen-Fuel Gas Systems for Welding, Cutting, and Allied Processes,* National Fire Protection Association, 2007
NFPA	51B	2009	NFPA 51B, *Fire Prevention During Welding, Cutting, and Other Hot Work,* National Fire Protection Association, 2009
NFPA	54	2009	NFPA 54, *National Fuel Gas Code, National Fire Protection Association,* 2009
NFPA	55	2005	NFPA 55, *Storage, Use, and Handling of Compressed Gases and Cryogenic Fluids in Portable and Stationary Containers, Cylinders, and Tanks,* National Fire Protection Association, 2005, with ERRATA 1 2006
NFPA	58	2008	NFPA 58, *Liquefied Petroleum Gas Code*, National Fire Protection Association, 2008
NFPA	69	2008	NFPA 69, *Standard on Explosion Prevention Systems,* National Fire Protection Association, 2008
NFPA	70	2008	NFPA 70, *National Electrical Code®,* National Fire Protection Association, 2008
NFPA	72	2007	NFPA 72®, *National Fire Alarm Code®*, National Fire Protection Association, 2007
NFPA	75	2009	NFPA 75, *Protection of Information Technology Equipment,* National Fire Protection Association, 2009
NFPA	80	2007	NFPA 80, *Standard for Fire Doors and Other Opening Protectives*, National Fire Protection Association, 2007
NFPA	80A	2007	NFPA 80A, *Protection of Buildings from Exterior Fire Exposures,* National Fire Protection Association, 2007

GLE Facility Design Code and Standards[1]			
Code Group / Reference	Code Number	Year or Edition	Title
NFPA	90A	2009	NFPA 90A, *Standard for the Installation of Air-Conditioning and Ventilating Systems*, 2009
NFPA	90B	2009	NFPA 90B, *Standard for the Installation of Warm Air Heating and Air-Conditioning Systems*, National Fire Protection Association, 2009
NFPA	91	2004	NFPA 91, *Exhaust Systems for Air Conveying of Vapors, Gases, Mists and Noncombustible Particulate Solids*, National Fire Protection Association, 2004
NFPA	92A	2006	NFPA 92A, *Standard for Smoke-Control Systems Utilizing Barriers and Pressure Differences*, 2006
NFPA	92B	2005	NFPA 92B, *Standard for Smoke Management Systems in Malls, Atria, and Large Spaces*, 2005
NFPA	101®	2009	NFPA 101®, *Life Safety Code®*, National Fire Protection Association, 2009
NFPA	105	2007	NFPA 105, *Standard for the Installation of Smoke Door Assemblies and Other Opening Protectives*, 2007
NFPA	110	2005	NFPA 110, *Standard for Emergency and Standby Power Systems*, National Fire Protection Association, 2005
NFPA	111	2005	NFPA 111, *Standard on Stored Electrical Energy Emergency and Standby Power Systems,* National Fire Protection Association, 2005
NFPA	220	2009	NFPA 220, *Standard on Types of Building Construction,* National Fire Protection Association, 2009.
NFPA	221	2009	NFPA 221, *Standard for High Challenge Fire Walls, Fire Walls, and Fire Barrier Walls*, National Fire Protection Association, 2009
NFPA	241	2009	NFPA 241, *Standard for Safeguarding Construction, Alteration, and Demolition Operations*, National Fire Protection Association 2009
NFPA	497	2008	NFPA 497, *Recommended Practice for the Classification of Flammable Liquids, Gases, or Vapors and of Hazardous (Classified) Locations for Electrical Installations in Chemical Process Areas*, 2008
NFPA	600	2005	NFPA 600, *Standard on Industrial Fire Brigades*, National Fire Protection Association, 2005
NFPA	704	2007	NFPA 704, *Standard System for the Identification of the Hazards of Materials for Emergency Response,* 2007
NFPA	780	2008	NFPA 780, *Standard for the Installation of Lightning Protection Systems,* National Fire Protection Association, 2008
NFPA	801	2008	NFPA 801, *Standard for Fire Protection for Facilities Handling Radioactive Materials*, National Fire Protection Association, 2008
NFPA	1620	2003	NFPA 1620, *Recommended Practice for Pre-Incident Planning*, National Fire Protection Association, 2003

GLE Facility Design Code and Standards[1]			
Code Group / Reference	**Code Number**	**Year or Edition**	**Title**
NFPA	2001	2008	NFPA 2001, *Standard on Clean Agent Fire Extinguishing Systems,* 2008
NRC		2007	*Environmental Assessment for Renewal of Special Nuclear Material License No. SNM-1097 General Electric Company Nuclear Energy Product Facility*, U.S. Nuclear Regulatory Commission, 2007
NRC	0609	2005	NRC Inspection Manual, 0609 Appendix F, *Fire Protection Significance Determination Process*. Issue Date: 2/28/05
NRC	FCSS-ISG-08		FCSS-ISG-08, *Natural Phenomena Hazards,* Revision 0, Interim Staff Guidance Document for Fuel Cycle Facilities, U.S. Nuclear Regulatory Commission, Washington D.C.
NRC Reg Guide	3.12	1973	*General Design Guide for Ventilations Systems of Plutonium and Fuel Fabrication Plants*, August 1973
NRC Reg Guide	3.71	2005, Rev. 1	*Nuclear Criticality Safety Standards Fuels and Material Facilities*, Revision 1, October 2005
NRC Reg Guide	8.24	1979, Rev. 1	*Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication*, Revision 1, October 1979
NUREG	0700	2002, Rev. 2	*Human-System Interface Design Review Guidelines*, Revision 2, May 2002
NUREG	1278	1983	NUREG-1278, *Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications*, March 1983
NUREG	1391	1991	NUREG-1391, *Chemical Toxicity of Uranium Hexafluoride Compared to Acute Effects of Radiation,* U.S. Nuclear Regulatory Commission, February 1991
NUREG	1513	2001	NUREG-1513, *Integrated Safety Analysis Guidance Document*, U.S. Nuclear Regulatory Commission, May 2001
NUREG/CR	6410	1998	NUREG/CR-6410, *Nuclear Fuel Facility Cycle Accident Analysis Handbook*. March 1998
NUREG/CR	6928	2007	NUREG/CR-6928, *Industry-Average Performance for Components and Initiating Events at U.S. Commercial Nuclear Power Plants*, February 2007
PCI	MNL-120	1999 Fifth Edition	*Precast Concrete Institute Design Handbook: Precast and Pre-Stressed Concrete*
SMACNA		2006	*HVAC Duct Construction Standards* - Metal and Flexible, 2006
SMACNA		2004	*Rectangular Industrial Duct Construction Standards*
SMACNA		1999	*Rounded Industrial Duct Construction Standards*
SMACNA		2003	*HVAC Air Duct Leakage Test Manual, First Edition*
SMACNA		2002	*HVAC Systems Testing, Adjusting, and Balancing - Third Edition*
UL	555	2006	UL555, *Standard for Fire Dampers*, 2006
UL	555S	2006	UL555S, *Standard for Smoke Dampers*, 2006

GLE Facility Design Code and Standards[1]			
Code Group / Reference	**Code Number**	**Year or Edition**	**Title**
UL	586	2000	UL586, *Standard for Safety High-Efficiency, Particulate, Air Filter Units*, 2000
UL	900	2007	UL900, *Standard for Safety Air Filter Units*, 2007

License Documentation Impact

The table and the preceding introductory paragraph will be added to Chapter 3 of the GLE License Application. The GLE ISA Summary Appendix A, Licensing Code of Record*, will reference the License Application.*

ISA-2 Section 3.2.4.3

Revise the license application to clarify the commitment to provide criticality accident alarm system (CAAS) coverage.

Section 3.2.4.3, states that areas where SNM is handled, used, or stored in amounts at or above the 10 CFR 70.24 mass limits have CAAS coverage. This statement is not entirely consistent with the regulatory requirements of 10 CFR 70.24.

Regulations in 10 CFR 70.24 require that licensees authorized to possess greater than a critical mass of SNM shall provide CAAS coverage in *each* area where SNM is handled, used, or stored. The license application requests authorization to possess greater than a critical mass of SNM, therefore, an exemption to 10 CFR 70.24 must be requested to exclude areas from CAAS coverage where SNM is handled, used, or stored. Such a request should specify the areas where CAAS coverage may not be provided and justify that the 10 CFR 70.17 requirements for granting an exemption are met.

GLE Response

As required by 10 CFR 70.24, the GLE facility "shall maintain in each area in which such licensed special nuclear material is handled, used, or stored, a monitoring system meeting the requirements of paragraphs (a)(1) or (a)(2), as appropriate, and using gamma- or neutron-sensitive radiation detectors which will energize clearly audible alarm signals if accidental criticality occurs". The areas in which SNM may be handled, used, or stored are identified in Section 1.1.2.1 and 1.1.2.2 of the license application. The license application will be revised to clarify the commitment to provide CAAS coverage in accordance with the above stated requirement.

Note that GLE is planning to request an exemption to the requirements of 10 CFR 70.74 for areas where very small quantities of SNM are present and/or in areas used only for onsite transfer and storage of fissile material that is packaged in DOT approved shipping containers in accordance with certificate requirements. This request will be submitted by January 29, 2010.

License Documentation Impact

The second sentence in Section 3.2.4.3 of the license application will be revised to include the following statement:

"CAAS coverage shall be provided in each process area where special nuclear material (SNM) is handled, used, or stored."

ISA-3 Section 3.2.5.8

Explain how likelihood index, T, is determined.

Section 3.2.5.8 and Table 3-7 both refer to likelihood index, T. However, no explanation is provided on how it is determined.

Regulations in 10 CFR 70.62(c)(v) require the identification of methods used to determine the consequences and likelihood of potential accident sequences.

GLE Response

Index numbers may be used as a simplified method in assessing the overall likelihood of an accident sequence. The likelihood index "T" is defined as the logarithm of the overall likelihood of an accident sequence (i.e., $log_{10}(L_T)$).

An overall likelihood of 10^{-5} per year (highly unlikely) has a likelihood index of -5. Indices may also be assigned to initiating event frequencies and IROFS failure probabilities. The index method is simplified method for expressing the frequency (or probability) of an event or control failure. The likelihood index is simply the sum of the initiating event (IE) an IROFS indices, whereas the overall likelihood is the product of the IE frequency and IROFS failure probabilities. Use of either method is acceptable; they are simply different ways to mathematically assess the frequency of the accident sequence occurrence.

For example: If the initiating event frequency is once in 10 years, and there are two IROFS to prevent a high consequence event, each with a probability of failure of 10^{-2}, then total overall likelihood (frequency) of the accident sequence may be expressed as follows;

Overall likelihood (L_T) = (10^{-1} / year) x (10^{-2}) x (10^{-2}) = 10^{-5} / year [Highly Unlikely]

OR…

Likelihood Index (T) = -1 + -2 + -2 = -5 [Highly Unlikely]

License Documentation Impact

The third paragraph of Section 3.2.5.8 of the license application will be revised as follows:

"The mitigated likelihood of the accident scenario occurring with the preventive or mitigating IROFS in-place must meet the requirements in 10 CFR 70.61, which requires that unacceptable consequences be limited. This is accomplished using index values, which are defined as the logarithm of the frequency (or probability) associated with the initiating event and subsequent IROFS failures for the accident scenario. The values of the index numbers for an accident scenario, depending on the number of events involved, are added to obtain a total likelihood index, "T." The likelihood index is therefore the logarithm of the overall likelihood (i.e., $\log_{10}(L_T)$). Accident scenarios are then assigned to one of the three likelihood categories of the risk matrix, depending on the value of the likelihood index in accordance with Table 3-6."

ISA-4 Glossary and Sections 3.2.5.3 and 3.2.5.8

Explain how nuclear criticality safety (NCS) controls relate to items relied on for safety (IROFS) and safeguards.

In the Glossary, "Safety Controls" are stated as being IROFS, and, in Section 3.2.5.8, it is stated that safety controls and IROFS are synonymous. In Section 3.2.5.3, it is stated that safeguards are design features or administrative programs that provide defense-in-depth, but are not credited as IROFS. In Chapter 5, "Nuclear Criticality Safety," the applicant refers to safety controls (i.e., NCS controls) and does not use the term "safeguards." This implies that all NCS controls are IROFS. However, it appears that many NCS controls may not be IROFS. This implies that NCS controls can either be IROFS or safeguards, which conflicts with the statements in the license application.

Regulations in 10 CFR 70.61(e) require that each control or control system necessary to comply with the performance requirements of 10 CFR 70.61 be designated as an IROFS.

GLE Response

Safeguard is a general term used in the ISA process used to describe a safety control. Safeguards may be controls used for any safety discipline (e.g., criticality, radiological, chemical, fire, etc…). Nuclear criticality safety (NCS) controls are safeguards that are implemented specifically to prevent an inadvertent criticality. Therefore, all NCS controls are safeguards but not all safeguards are NCS controls.

IROFS are safety controls that are relied on to prevent credible accident sequences at the facility from occurring that could exceed the performance requirements in 10 CFR 70.61 or mitigate their potential consequences. The safeguards identified in the ISA process that are required to meet the performance requirements in 10 CFR 70.61 are declared as IROFS.

Any additional safeguards are defense-in-depth and are not required to be declared as IROFS. As such, the NCS controls that are necessary to maintain the system subcritical under normal and credible abnormal conditions and achieve an overall likelihood of less than or equal to 10^{-5} per year (per event), are required to be declared as IROFS in the ISA summary. The response to question NCS-001 further explains the process of determining which NCS controls are required to be declared as IROFS.

License Documentation Impact

The Front Matter of the license application will be revised to include the following definitions:

“**Items Relied on for Safety (IROFS)** – Structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in 10 CFR 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety. [10 CFR 70.4]”

“**Nuclear Criticality Safety (NCS) Control** – A fixed physical design feature, active device, or procedure that is implemented to maintain safe process conditions. NCS controls are preventive and may be passive engineered, active engineered, or administrative (procedural). The NCS controls that are necessary to maintain the system subcritical under normal and credible abnormal conditions and achieve an overall likelihood of less than or equal to 10^{-5} per year (per event), are declared as IROFS in the ISA summary.”

“**Safety Control (Safeguard)** – A system, device, or procedure that is intended to regulate a device, process, or human activity to maintain a safe state. Controls may be engineered controls or administrative (procedural) controls, and may be either preventive or mitigative.”

ISA-5 Section 3.2.6

Revise the license application to indicate that a qualified NCS engineer will be included on the ISA team.

Section 3.2.6, provides a discussion of the ISA team members. It is unclear that the ISA team requires someone with sufficient expertise in NCS to ensure that the ISA will adequately address NCS hazards.

Regulations in 10 CFR 70.62(c)(2) require that the ISA team include people with experience in NCS.

GLE Response

A qualified NCS engineer was included on each of the ISA teams during development of the initial ISA summary. The commitment in Section 3.2.6 of the license application was intended to require a qualified NCS engineer to be included on each ISA team. The license application will be revised to clarify this commitment to demonstrate compliance with 10 CFR 70.62(c)(2).

License Documentation Impact

Section 3.2.6 of the license application will be revised to include the following statement:

“A qualified NCS engineer will be included on each ISA team.”

Human Factors

HFE-1 Sections 3.2.5.8 and 6.2.1

Provide a Human Factors Engineering (HFE) program plan that describes the planned activities such as task analysis, staffing analysis, human-system interface (HSI) design, verification and validation, using the element structure in “Human Factors Engineering Program Review Model,” NUREG-0711.

Section 6.2.1 states that schemes to ensure safe operation include management measures, such as “procedures, training, human factors.” The applicant’s letter, dated September 4, 2009, responding to a request for information related to the acceptance review, states that an insert will be added to Section 3.2.5.8 that states in part that, for IROFS, a HFE review of the HSI shall be conducted using the applicable guidance in “Human System Interface Design Review Guidelines,” NUREG-0700, and NUREG-0711.

The regulations in 10 CFR 70.61(e) require a safety program that ensures each IROFS will be available and reliable.

GLE Response

GLE will provide an HFE Program Plan by March 30, 2010. The plan will address the twelve HFE elements as applicable to IROFS using the HFE Program element structure presented NUREG-0711, “Human Factors Engineering Program Review Model.”

License Documentation Impact

None

HFE-2 Section 3.2.5.8

Discuss how operating experience will be utilized, whether or not there is a specific predecessor plant.

The applicant’s letter, dated September 4, 2009, responding to a request for information related to the acceptance review, states that an insert will be added to Section 3.2.5.8 that states in part that, for IROFS, an HFE review of the HSIs will be conducted using the applicable guidance in NUREG-0700 and NUREG-0711. The Operating Experience Review element of NUREG-0711 focuses on operating experience as a key part of the HSI design process and includes the consideration of human factors issues from similar plants and similar systems within a plant. It also addresses operating experience for planned human factors engineering technology such as operator interfaces.

The regulations in 10 CFR 70.61(e) require a safety program that ensures each IROFS will be available and reliable.

GLE Response

During the design development that supported the initial ISA of the CF, several members of the ISA Team brought to the ISA Team direct operating experience from the Paducah, *Portsmouth, and/or Oak Ridge Gaseous Diffusion Plants. This experience was applied to the Phase I design of the various nodes and development of accident sequences used in the ISA. With the exception of the operation of the separators in the cascade, the other operations of the GLE enrichment process are similar to, or identical in nature to, that of an operating gaseous diffusion plant.*

Documents generated over the past 60+ years of operation of the gaseous diffusion plants have been made public while other documents are available on request from DOE (based on need to know). These items have been and continue to be utilized as a basis for operating experience, applicable to the design of the GLE Commercial Facility. During development of the core technology of the laser enrichment process provided to GLE by SILEX and during the construction and operation of the Test Loop at GNF-A in Wilmington, North Carolina, additional operating experience about the process characteristics is being collected. This information is available for the CF design, construction, testing, procedure development, training, and operation.

During development of the CF Technical Design Baseline (which consists of the documents produced to support the development of the ISA including process or block flow diagrams, facility layout drawings, design criteria documents, and various technical reports), the design team utilized operating experience from the gaseous diffusion plants and the centrifuge plants in operation globally. Several key design philosophies were identified during the initial operating experience review of these existing production facilities. These include, but are not limited to, the design commitments to: maintain the UF_6 process in the solid or gaseous state except where standards required a liquid process (as in UF_6 cylinder sampling), to use non-hydrogenous coolants and lubricants adjacent to or in contact with UF_6 systems (for example, no hydrogenous oil seal pumps and no steam heated autoclaves); to maintain the UF_6 cylinder sampling system an automated, enclosed system with as few penetrations and minimal operator interface as possible (vessel tilt sampling concept with limited user interface and sample or cylinder handling while liquid); and to operate UF_6 systems at less than atmospheric pressure throughout the CF.

The HFE Plan will provide a description of the operating experience review (OER) and the technical reports for each node will be updated to more clearly document the OER evaluation that was conducted as part of the design.

GLE will provide an HFE Program Plan by March 30, 2010. The plan will address the applicable HFE elements using the element structure in NUREG-0711, "Human Factors Engineering Program Review Model."

License Documentation Impact

None

HFE-3 Section 3.2.5.8

Clarify the use of NUREG-0700 and NUREG-0711 for HSI design.

The applicant's letter, dated September 4, 2009, responding to a request for information related to the acceptance review, states that an insert will be added to Section 3.2.5.8 that states in part that, for IROFS, an HFE review of the HSIs will be conducted using the applicable guidance in NUREG-0700 and NUREG-0711. NUREG-0700 is written to provide review guidelines for NRC in reviewing HSIs. In order to meet the acceptance criteria of NUREG-0700/0711, HSI design guidelines or an HSI style guide needs to be provided by the design organization (in this case GEH) to actually perform the HIS design, not just review it. Please discuss your plans in this area.

The regulations in 10 CFR 70.61(e) require a safety program that ensures each IROFS will be available and reliable.

<u>GLE Response</u>

The HFE Plan will address the application of applicable elements of NUREG 0711 for the augmented administrative control type IROFS that require human system interface to accomplish the safety function. NUREG-0700 will be used to assist in the design of these types of IROFS. Additionally, HSI issues will be addressed during design of functional testing and calibration of Active Engineered Controls designated as IROFS, again applying the elements of the HFE Plan. The HFE features, including HSI design attributes, identified for each IROFS will be documented in the IROFS Boundary Definitions Package for each IROFS.

Based on the outputs of functional and task analysis associated with IROFS, the designers will identify the various types of HSIs, e.g., alarms, displays, and controls needed to perform the function reliably and utilize the appropriate guidelines for those HSI features identified in appropriate industry standard guidelines including applicable review guidance in NUREG-0700 on alarms (Section 4.0), local control panels (Section 12.2), control devices (Section 3.3), and parameter monitoring (Section 5.0). Currently, GLE does not anticipate any IROFS that require control from digital display systems.

Commitment to these HSI design elements will be provided in the HFE Program Plan. GLE will provide an HFE Program Plan by March 30, 2010. The plan will address the applicable HFE elements using the element structure in NUREG-0711, "Human Factors Engineering Program Review Model.*"*

<u>License Documentation Impact</u>

None

Radiation Protection (Chapter 4)

RP-1 Section 4.1

Commit to 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

Section 4.7.12 of the application describes the use of National Institute of Standards and Technology (NIST) traceable sources to be used for instrument calibrations. Because byproduct material will be used as calibration sources, it is necessary to comply with the requirements of 10 CFR Part 30.

The regulations in 10 CFR Part 30 apply to the use of byproduct material.

GLE Response

GLE fully intends to comply with 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct material", but the commitment was inadvertently left out of Chapter 4.

License Documentation Impact

LA Chapter 4 Section 4.1 will be revised as follows to commit to and reference 10 CFR Part 30 "Rules of General Applicability to Domestic Licensing of Byproduct material":

"4.1 RADIATION PROTECTION PROGRAM

The purpose of this chapter is to define the GE-Hitachi Global Laser Enrichment LLC (GLE) Radiation Protection (RP) Program. The RP Program protects the radiological health and safety of workers and the public and complies with the following:

- 10 CFR 19, Notices, Instructions, and Reports to Workers: Inspection and Investigations
- 10 CFR 20, Standards for Protection Against Radiation (Ref. 4-2),
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."
- 10 CFR 70, Domestic Licensing of Special Nuclear Material (Ref. 4-3), and
- Regulatory Guide 8.2, Guide for Administrative Practices in Radiation Monitoring

The RP Program also provides protection to workers in the event of an accident as defined in the Integrated Safety Analysis (ISA)."

RP-2 Section 4.2

Modify the effluent release principle to state that radiation exposures shall be monitored and the annual average release concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area will not exceed the values in Table 2 of Appendix B of 10 CFR Part 20.

In Section 4.2, the applicant committed to an As Low As Reasonably Achievable (ALARA) program, but did not specifically state that it would meet the effluent release requirements in Table 2 of Appendix B to 10 CFR Part 20. In addition, in Section 4.2.1, the applicant committed to using Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities" (RG 8.37). RG 8.37 recommends that the annual average release concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area will not exceed the values in Table 2 of Appendix B of 10 CFR Part 20.

Regulations in 10 CFR 20.1302 require that licensees make or cause to be made appropriate radiation surveys of radioactive effluents in accordance with Table 2 of Appendix B to 10 CFR Part 20.

GLE Response

LA Section 4.2.1 will be revised to incorporate "radiation exposures shall be monitored and the annual average release concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area in compliance with 10CFR 20.1302 and will not exceed the values in Table 2 of Appendix B of 10 CFR Part 20.

License Documentation Impact

LA Section 4.2.1 first paragraph will be revised as follows:

"The design and implementation of the ALARA Program is consistent with the guidance contained in Regulatory Guide 8.2, Regulatory Guide 8.13, *Instruction Concerning Prenatal Radiation Exposure (Ref. 4-12)*, Regulatory Guide 8.29, *Instruction Concerning Risks from Occupational Radiation Exposure (Ref. 4-13)*, and Regulatory Guide 8.37, *ALARA Levels for Effluents from Materials Facilities (Ref. 4-14)*. Radiation exposures shall be monitored and the annual average release concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area in compliance with 10CFR 20.1302 and will not exceed the values in Table 2 of Appendix B of 10 CFR Part 20."

RP-3 Section 4.2

Specify which GEH facility manager is responsible for the ALARA program.

Section 4.2 does not indicate which GEH manager is responsible for the ALARA program as recommended in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable," which the applicant committed to in Section 4.12.

The regulations in 10 CFR 20.1101(b) require that licensee use, to the extent practicable, procedures and engineered controls to achieve occupational doses and doses to the public that are ALARA.

GLE Response

GLE will follow the recommendation in Regulatory Guide 8.10 and revise the Section to indicate that the GLE President and CEO is ultimately responsible for the ALARA program.

License Documentation Impact

The first paragraph in Section 4.2.3 will be revised as follows:

"In accordance with 10 CFR 20.1101, the RP Program is designed to achieve occupational and public doses that are ALARA. The GLE President and CEO provides overall direction and management with the respect to design, construction, operation, and decommissioning activities. This individual is responsible for ensuring the facility complies with all applicable regulatory requirements, ALARA principles and establishing the basic policies of the radiation control program. The RP Manager is responsible for implementation of the ALARA Program. The RSC provides oversight of the RP Program as described in Section 4.2.4, Radiation Safety Committee. In order to keep exposures ALARA, the following principles guide the RP Program:

- Radiation exposures and the release of radioactive effluents shall be monitored.
- Individual exposures shall be controlled to be less than applicable regulatory limits."

RP-4 Section 4.5.6

Modify your process for evaluating personnel training to include a practical assessment for certain employees, in addition to a computer-based test.

In Section 4.5.1, the applicant committed to conducting a radiation protection training program consistent with American Society for Testing and Materials (ASTM) ASTM E1168-95, "Standard Guide for Radiological Protection Training for Nuclear Facility Workers." Section 5.4.2 of ASTM E1168 requires that "workers whose radiological protection depends on their effective use of equipment, facilities, or specialized procedures shall be observed by a qualified trainer while using such equipment and shall be individually graded."

Regulations in 10 CFR 19.12 require licensees to provide instructions to workers on radiation safety.

GLE Response

GLE intends to follow the guidance in American Society for Testing and Materials (ASTM) ASTM E1168-95, "*Standard Guide for Radiological Protection Training for Nuclear Facility Workers.*" Workers whose radiological protection depends on their effective use of equipment, facilities, or specialized procedures shall be observed by a qualified trainer while using such equipment and shall be individually graded.

License Documentation Impact

LA section 4.5.1 will be revised as follows:

"4.5.1 Design and Implementation of Radiation Protection Training Program

The RP Training Program is designed and implemented to be consistent with the guidance in ASTM E1168-95. Workers whose radiological protection depends on their effective use of equipment, facilities, or specialized procedures shall be observed by a qualified trainer while using such equipment and shall be individually graded. As described in Section 4.5.3, *Level of Training*, the RP Training Program is compliant with regulations in 10 CFR 19.12, *Instruction to Workers (Ref. 4-18)*, and 10 CFR 20.2110, *Form of Records (Ref. 4-19)*."

RP-5 Section 4.6.1.1

Provide the codes and standards to be used for design, fabrication, installation, and testing of the ventilation systems.

Section 4.6.1.1 provides a general description of the ventilation systems, but does not describe the codes and standards to be used for system design, fabrication, installation, and testing.

The regulations in 10 CFR 20.1701 require a licensee to utilize engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in the air.

GLE Response

*The items that are highlighted are **directly** related to HVAC design, fabrication, and testing. The other codes and standards are indirectly related. These codes and standards are included in the response to ISA-001.*

GLE Facility Design Code of Record

Ref No.	Code Group / Reference	Code Number	Year or Edition	Title
	ACGIH		2007	*Industrial Ventilation: A Manual of Recommended Practice*
	ANSI/AIHA	Z9.5	2003	*Laboratory Ventilation*
	ANSI / ASME	ANSI/ASME AG-1 (Section FC-5160)	2003	ANSI/ASME AG-1 (Section FC-5160), *Code on Nuclear Air and Gas Treatment*, ASME International, 2003.
	ANSI/ASME	B31.9	2008	ANSI/ASME B31.9, *Building Services Piping*, 2008
	ASME	ASME N510	2007	Testing of Nuclear Air Treatment Systems, 2007
	ASHRAE	62	2001	ASHRAE 62, V*entilation for Acceptable Indoor Air Quality*, 2001
	ASHRAE	90.1	2001	ASHRAE 90.1, *Energy Standard for Buildings Except Low-Rise Residential Buildings*, 2001
	ASHRAE	90A	1980	The American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) Standard 90A, *Energy Conservation in New Building Design*, 1980
	ASTM	E814	2008	ASTM E814, 2008B Standard test method for fire tests of Penetration Firestop Systems.

	ICC	NCBC	2009	2006 ICC *International Plumbing Code, IPC* w/2009 NC Amendments
	ICC	NCBC	2009	2006 ICC *International Mechanical Code, IMC* w/2009 NC Amendments
	ICC	NCBC	2009	North Carolina State Building Codes, Version 1.0, 2009 2006 ICC International Building Code w/2009 NC Amendments
	ICC	NCFC	2009	North Carolina Fire Code IFC - 2006 w/2009 NC Amendments
	NFPA	72	2007	NFPA 72®, *National Fire Alarm Code®*, National Fire Protection Association, 2007
	NFPA	90A	2009	NFPA 90A, *Standard for the Installation of Air-Conditioning and Ventilating Systems*, 2009
	NFPA	90B	2009	NFPA 90B, *Standard for the Installation of Warm Air Heating and Air-Conditioning Systems*, National Fire Protection Association, 2009
	NFPA	91	2004	NFPA 91, *Exhaust Systems for Air Conveying of Vapors, Gases, Mists and Noncombustible Particulate Solids*, National Fire Protection Association, 2004
	NFPA	92A	2006	NFPA 92A, *Standard for Smoke-Control Systems Utilizing Barriers and Pressure Differences*, 2006
	NFPA	92B	2005	NFPA 92B, *Standard for Smoke Management Systems in Malls, Atria, and Large Spaces*, 2005
	NFPA	801	2008	NFPA 801, *Standard for Fire Protection for Facilities Handling Radioactive Materials*, National Fire Protection Association, 2008
	NUREG	3.12	1973	NUREG 3.12, *General Design Guide for Ventilations Systems of Plutonium and Fuel Fabrication Plants*, 1973

	SMACNA		2006	*HVAC Duct Construction Standards* - Metal and Flexible, 2006
	SMACNA		2004	*Rectangular Industrial Duct Construction Standards*
	SMACNA		1999	*Rounded Industrial Duct Construction Standards*
	UL	555	2006	UL555, *Standard for Fire Dampers*, 2006
	UL	555S	2006	UL555S, *Standard for Smoke Dampers*, 2006
	UL	586	2000	UL586, *Standard for Safety High-Efficiency, Particulate, Air Filter Units*, 2000
	UL	900	2007	UL900, *Standard for Safety Air Filter Units*, 2007

License Documentation Impact

Chapter 3 will be revised in response to RAI Question ISA-1 to include the above codes and standards.

RP-6 Section 4.6.2.2.3

Specify that determination of medical fitness to use respiratory protection equipment will be made by a physician.

The regulations in 10 CFR 20.1703(c)(5) require that a physician make such a medical determination.

GLE Response

GLE will have a physician make the determination fitness to use respiratory protection equipment.

License Documentation Impact

LA chapter 4 section 4.6.2.2.3 will be revised as follows:

"**4.6.2.2.3 Issuance of Respiratory Protection Equipment**

Approved written procedures prescribe the actions to be taken when issuing respiratory protection equipment. In accordance with 10 CFR 20.1703(c)(5), individuals designated to use respiratory protection equipment are evaluated by the Medical function to determine if the individual is medically fit to use respiratory protection devices. The determination of medical fitness to use respiratory protection equipment will be made by a physician. Individuals are evaluated periodically thereafter, at a frequency specified by the Medical function."

RP-7 Section 4.7.12

Provide additional detail for calibrating radiation instruments (e.g., codes and standards to be used, use of contractor services, etc.).

Section 4.7.12 provides insufficient information on instrument calibration. In Section 4.7, you commit to Regulatory Guide 8.2, "Guide for Administrative Practices in Radiation Monitoring," which refers to American National Standards Institute (ANSI) ANSI N13.2, "Guide for Administrative Practices in Radiation Monitoring." In Section 4.7.2 of ANSI N13.2, the standard states that calibration services can be contracted, or they can be developed in-house. Specify which manner your calibration services will be completed. Consider committing to ANSI N323, "Radiation Protection Instrumentation Test and Calibration."

Regulations in 10 CFR 20.1501(b) require that instruments and equipment used for quantitative radiation measurements be periodically calibrated for the radiation measured.

GLE Response

LA chapter 4, section 4.7.12 will be revised to include a statement committing to ANSI N323 "Radiation Protection Instrumentation Test and Calibration" and a statement clarifying that calibration may take place in house or be performed by a qualified subcontractor.

License Documentation Impact

LA Chapter 4 section 4.7.12 will be revised as follows:

"**4.7.12 Equipment and Instrumentation Sensitivity**

Appropriate radiation detection instruments are available in sufficient number to ensure adequate radiation surveillance can be accomplished. Selection criteria for portable and laboratory counting equipment are based on the types of radiation detected, maintenance requirements, ruggedness, interchangeability, and upper and lower limits of detection capabilities. The RP staff reviews the appropriateness of the types of instruments being used for each monitoring function annually. Table 4-3, *Types and Uses of Available Instrumentation (Typical)*, lists examples of the types and uses of available instrumentation and includes the type of equipment, the sensitivity (typical range), and the routine use.

Portable instrumentation is calibrated in accordance with ANSI N323, "Radiation Protection Instrumentation Test and Calibration" and manufacturing recommendations before initial use, after major maintenance, and on a routine basis following the last calibration. Calibration consists of a performance check on each range scale of the instrument with a radioactive source of known activity traceable to a recognized standard such as the National Institute of Standards and Technology (NIST). In accordance with section 4.7.2 of ANSI N13.2 the calibration services may be contracted or developed in-house. Prior to each use, operability checks are performed on monitoring and laboratory counting instruments. The background and efficiency of laboratory counting instruments are determined on a daily basis when used."

RP-8 Section 4.7.14

Provide information on sealed source inventory and leak testing procedures.

Section 4.7.14 states that sealed sources will be inventoried periodically and leak tested in accordance with International Standards Organization (ISO) ISO-2919, “Radiation Protection – Sealed Sources – General Requirements and Classification.” ISO 2919 does not describe inventory or leak testing procedures.

The regulations in 10 CFR 31.5(c)(2) require that leak tests will be done on 6 month intervals. Leak test recommendations are given in Branch Technical Position, “License Condition for Leak-Testing Byproduct Material Sources,” April 1993.

GLE Response

LA chapter 4 section 4.7.14 will be revised to delete the reference to International Standards Organization (ISO) ISO-2919, “*Radiation Protection – Sealed Sources – General Requirements and Classification*” and replace it with Branch Technical Position, “*License Condition for Leak-Testing Byproduct Material Sources*,” April 1993 and Regulatory Guide 8.24 “*Health Physics surveys during enriched uranium-235 processing and fuel fabrication*”.

License Documentation Impact

LA chapter 4 section 4.7.14 will be revised as follows:

“**4.7.14 Sealed Sources**

When not in use, sources shall be stored in a closed container adequately designed and constructed to contain radioactive material that may otherwise be released during storage. Sealed sources are controlled and periodically inventoried. The sources shall be leak-tested in accordance with the Branch Technical Position, “License Condition for Leak-Testing Byproduct Material Sources,” April 1993 and Reg Guide 8.24 “Health Physics surveys during enriched uranium-235 processing and fuel fabrication.”

Nuclear Criticality Safety (Chapter 5)

NCS-1 Sections 5.1 and 5.4.2

Clarify how the criticality safety analyses (CSAs) will demonstrate that processes will remain subcritical under normal and credible abnormal conditions. Explain how the ISA process will ensure that NCS IROFS alone (i.e., without reliance upon other NCS controls or controlled parameters) will ensure that processes will remain subcritical under normal and credible abnormal conditions.

Sections 5.1 and 5.4.2 imply that the CSAs will demonstrate compliance with the double contingency principle and that this is the only method GEH will use to demonstrate that processes will remain subcritical under normal and credible abnormal conditions. This suggests that controls identified for double contingency purposes would then be declared as IROFS. It is unclear if this is the intent since it is not clearly stated in the license application.

Regulations in 10 CFR 70.61(d) require that all nuclear processes be subcritical under both normal and credible abnormal conditions. 10 CFR 70.61(e) requires that each control or control system necessary to comply with 10 CFR 70.61(d) be designated as an IROFS.

GLE Response

The purpose of the criticality safety analysis (CSA) is to demonstrate compliance with 10 CFR 70.64(a)(9), the double contingency principle, through control of one or more parameters important to criticality safety. The parameters to be controlled and the controls on specified parameters are determined and evaluated in the CSA. The controls specified in the CSA may be passive engineered, active engineered, or administrative. Additional requirements for management measures such as postings, periodic inspections, and maintenance requirements are also specified in the CSA to assure the NCS controls are available and reliable. In many cases, the CSA incorporates additional controls that are not required to meet double contingency, but provide defense-in-depth for the system being evaluated. Application of the double contingency principle assures that the process will remain subcritical under normal and credible abnormal conditions. The identified normal and credible abnormal conditions are analyzed using a validated calculational method to demonstrate that the system will remain subcritical including an approved margin of safety.

The CSA therefore demonstrates that the process will remain subcritical under normal and credible abnormal conditions through application of the double contingency principle. However, the CSA does not demonstrate that each credible criticality accident sequence is "highly unlikely" as defined in Chapter 3 of the license application. This is accomplished through the ISA process itself and is necessary to assure that the "risk of nuclear criticality accidents is limited" in accordance with 10 CFR 70.61(d). The CSA is an integral part of the ISA process, and is instrumental in determining the credible accident sequences and criticality controls that protect against the criticality accident sequences. Each credible criticality accident sequence is documented in the Process Hazards Analysis (PHA), the consequence (i.e., criticality) is specified, the severity and unmitigated likelihood are assessed by the ISA Team, and the NCS controls protecting against the accident sequence are identified. These controls are called out as "safeguards" in the PHA.

For each credible criticality accident sequence the severity of the consequence is high and therefore an evaluation must be performed to determine which NCS controls must be declared as IROFS to meet the overall likelihood requirement of 10^{-5} per year (i.e., highly unlikely).

The assessment of overall likelihood for each credible criticality accident sequence is performed in the Quantitative Risk Assessment (QRA) [refer also response ISA-003 above]. The initiating event (IE) frequency is assessed in the QRA and IROFS are applied to reduce the overall likelihood of the accident to less that of equal to 10^{-5} per year.

The preferred hierarchy of controls that are selected to be criticality IROFS is as follows; 1) passive engineered, 2) active engineered, and 3) administrative. As specified in Section 5.1 of the license application, "the engineered and administrative NCS control required to prevent an inadvertent nuclear criticality and meet the overall likelihood requirements specified in GLE LA Chapter 3, Integrated Safety Analysis, are designated as Items Relied on for Safety (IROFS)". The NCS controls identified as IROFS are those that are needed to meet these requirements, which assures compliance with 10 CFR 70.61. Other NCS controls, that are not needed to meet these requirements, but that provide defense-in-depth to further reduce the risk of a criticality, are not required to be designated as IROFS.

QRA documents governing criticality accident sequences (that specify NCS IROFS) are reviewed by a qualified NCS engineer to assure the IROFS selected are appropriate to maintain the system subcritical for each credible accident sequence evaluated.

License Documentation Impact

The second paragraph of Section 5.1.1 will be revised as follows:

"The established NCS design criteria and NCS reviews are applicable to: (1) new and existing processes, facilities, or equipment which process, store, transfer, or otherwise handle fissile materials; and (2) any change in existing processes, facilities, or equipment which may have an impact on the established basis for NCS. For fissile material operations, double contingency protection may be provided by either control of at least two independent parameters, or control of a single parameter using a system of multiple independent controls. The defense of one or more system parameters provided by at least two independent controls is documented in the GLE Criticality Safety Analyses (CSAs). The purpose of the criticality safety analysis (CSA) is to demonstrate compliance with 10 CFR 70.64(a)(9), the double contingency principle, through control of one or more parameters important to criticality safety. The parameters to be controlled and the controls on specified parameters are determined and evaluated in the CSA. The controls specified in the CSA may be passive engineered, active engineered, or administrative. Additional requirements for management measures such as postings, periodic inspections, and maintenance requirements are also specified in the CSA to assure the NCS controls are available and reliable. Application of the double contingency principle assures that the process will remain subcritical under normal and credible abnormal conditions."

NCS-2 Section 5.3.5

Commit to maintain a documented evaluation that demonstrates the CAAS meets the requirements of 10 CFR 70.24.

Information is needed to ensure a CAAS is in place that will adequately meet the requirements of 10 CFR 70.24.

Regulations in 10 CFR 70.24 require a CAAS be maintained in each area where SNM is handled, used, or stored for facilities authorized to possess greater than a critical mass of SNM.

GLE Response

The CAAS system will be designed to meet the requirements of 10 CFR 70.24 prior to introduction of SNM at the facility. An evaluation that demonstrates compliance with the CAAS requirements of 10 CFR 70.24 will be documented and maintained under configuration management. When complete, the evaluation will be made available of NRC review.

License Documentation Impact

The first paragraph of Section 5.3.5 of the license application will be revised as follows:

"The Criticality Accident Alarm System (CAAS) is designed and maintained to ensure compliance with requirements in 10 CFR 70.24, *Criticality Accident Requirements (Ref. 5-10)*, and ANSI/ANS 8.3-1997, *Criticality Accident Alarm System (Ref. 5-11)* as modified by Regulatory Guide 3.71, *Nuclear Criticality Safety Standards for Fuels and Material Facilities (Ref. 5-12)*. An evaluation that demonstrates compliance with the CAAS requirements of 10 CFR 70.24 is documented and maintained under configuration management. The location and spacing of the detectors are selected taking into account shielding by massive equipment or materials. Spacing between detectors is reduced where high-density building materials such as brick, concrete, or grout-filled cinder block shield a potential accident area from the detector. Low-density materials of construction, such as wooden stud construction walls, plaster, or metal corrugated panels, doors, non-load walls, and steel office partitions, are accounted for with conservative modeling approximations in determining detector placement."

NCS-3 Section 5.3.5

Commit to design the CAAS such that it complies with Paragraphs 5.2 and 5.3 of ANSI/ANS-8.3-1997, "Criticality Accident Alarm System," or provide justification for not doing so.

As this is a new facility, it is expected that the CAAS will be designed to remain operational during a design basis earthquake, fires, and other credible events.

Regulations in 10 CFR 70.24 require that licensees authorized to possess greater than a critical mass of SNM shall provide CAAS coverage in each area where SNM is handled, used, or stored. 10 CFR 70.64(a) requires that the design of the facility protect against natural phenomenon, fire, explosion, environmental, and dynamic effects.

GLE Response

Since these criteria for system design are specified as recommendations in ANSI/ANS-8.3-1997 (shall statements) the current license application commitment to ANSI/ANS-8.3-1997 does not adequately capture them as requirements. The license application will be updated to specifically call out these criteria for system design as requirements for the CAAS system.

License Documentation Impact

The list of commitments in Section 5.3.5 of the license application will be revised to include the following as CAAS requirements based on the recommendations specified in Paragraphs 5.2 and 5.3 of ANSI/ANS-8.3-1997:

"GLE commits to having a CAAS that:

- Have components that are located or protected to minimize damage in case of fire, explosion, corrosive atmosphere, or other credible extreme conditions.

- Is designed to minimize the potential failure, including false alarms, due to human error and has major system components labeled.

- Is designed to remain operational in the event of seismic shock equivalent to the site-specific design basis earthquake, or the Uniform Building Code that applies to the structure.

- Is uniform throughout the facility for the type of radiation detected, mode of detection, alarm signal, and system dependability;

- Provides coverage in each area that needs CAAS coverage by a minimum of two detectors; and

- Is clearly audible in areas that must be evacuated, or provides alternate visual notification methods documented to be effective in notifying personnel of a necessary evacuation."

NCS-4 Section 5.4.1.3

Commit to only reject data outliers in the NCS code validation based upon inconsistency of the data with known physical behavior.

Paragraph 6.3.2 of ANSI/ANS-8.24-2007, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations," permits the rejection of data outliers using established statistical rejection methods. The NRC staff position is that the rejection of outliers using statistical methods alone may eliminate an important aspect of the physical system that is important to the validation.

Regulations in 10 CFR 70.61(d) require that all nuclear processes be subcritical under both normal and credible abnormal conditions, including use of an approved margin of subcriticality for safety.

GLE Response

GLE understands the NRC staff position on the rejection of outliers as it relates to validation and will incorporate the requested commitment in the license application.

License Documentation Impact

The list of commitments related to selection of critical experiments in Section 5.4.1.3 of the license application will be revised to include the following statement:

"Data outliers in results obtained for the critical experiments selected for the validation may only be rejected based upon inconsistency of the data with known physical behavior."

NCS-5 Section 5.4.1.3.2

Revise the license application to include either (1) the additional methods used to determine the bias uncertainty or (2) the criteria for selection of such methods. Explain how it is determined that the use of an additional method is necessary.

Section 5.4.1.3.2 states that the bias uncertainty may be estimated using one of three specified statistical methods or additional methods when necessary. The additional methods are not specified.

Regulations in 10 CFR 70.61(d) require that all nuclear processes be subcritical under both normal and credible abnormal conditions, including use of an approved margin of subcriticality for safety.

GLE Response

The fourth method that may be utilized in assessing the bias uncertainty is a non-parametric method, which may include additional administrative margin. The proprietary statistical method has been described in the GEMER Monte Carlo Validation Report, which has been provided to the NRC. A brief non-proprietary description of this method will be included in the license application.

License Documentation Impact

Section 5.4.1.3.2 of the license application will be revised to include the following description of the fourth method for determination of bias uncertainty:

"Non-Parametric Method: Estimates the bias uncertainty to ensure, at a 95% level of confidence, that future calculations of k_{eff} for critical systems or processes are actually above the lower tolerance limit. This statistical technique is based on a rank order analysis of the data. When the sample size is insufficient to obtain a 95% confidence level using the statistical method, additional non-parametric margin is applied to assure the desired degree of confidence is achieved. The non-parametric technique is applied in cases where the calculated critical benchmark results (non-trending data) or the residuals of bias regression (trending data) fail the normality test."

The following statement in section 5.4.1.3.2 of the license application will be deleted:

"Additional methods may be used when necessary."

NCS-6 Section 5.4.1.4

Revise the license application to include the criteria or methods used to extend the area of applicability.

Section 5.4.1.4 states that any extrapolation beyond the area of applicability should be supported by an established mathematical method or sound engineering judgment.

Regulations in 10 CFR 70.61(d) require that all nuclear processes be subcritical under both normal and credible abnormal conditions, including use of an approved margin of subcriticality for safety.

GLE Response

The statistical method used to determine the acceptable extrapolation in the area of applicability is described in the GEMER validation report, which has been provided to the NRC. A brief description of this method will be included in the license application with further detail provided in the GEMER validation report.

License Documentation Impact

The sixth bullet in Section 5.4.1.4 of the license application will be revised as follows:

"Summarize the range in (or values of) NCS parameters describing the area of applicability. The area of applicability should be consistent with the values of parameters used in selected benchmark experiments. Any extrapolation beyond the area of applicability should be supported by an established mathematical methodology or sound engineering judgment. The mathematical method used for to determine the acceptable extrapolation limit for a regression model is the leverage statistic. The leverage statistic is a measure of the distance between the extrapolation point for a predication and the mean of trending parameter values in the critical benchmark data set. For a predication by extrapolation to be considered reliable with the predefined confidence level, its leverage value should not exceed the largest leverage value in the benchmark data set."

NCS-7 Section 5.4.4.1

Clarify the criteria for establishing safe mass limits based upon the minimum critical mass.

Section 5.4.4.1, states that a mass limit may be based upon 45 or 75 percent of the minimum critical mass, depending upon the situation. Is the minimum critical mass based upon handbook values? What assumptions regarding other parameters such as geometry, reflection, and chemical form are used?

Regulations in 10 CFR 70.61(d) require that all nuclear processes be subcritical under both normal and credible abnormal conditions, including use of an approved margin of subcriticality for safety.

GLE Response

When mass limits are determined based on an appropriate percentage of the minimum critical mass, as defined in Section 5.4.4.1 of the license application, the minimum critical mass must be selected from industry-accepted handbooks. Such handbooks *include, but not limited to, ARH-600 “Criticality Handbook”, LA-12808 “Nuclear Criticality Safety Guide”, and K-1019 “Criticality Data and Nuclear Safety Guide Applicable to the Oak Ridge Gaseous Diffusion Plant. For the purpose of deriving mass limits the following assumptions are applicable to the minimum critical mass; 1) spherical geometry, 2) full water reflection, 3) optimal moderation content, and 4) maximum credible enrichment. In addition, the chemical and physical form specified in the handbook must be at consistent with, or more restrictive than, that which may be present in the actual system to which the limit will be applied.*

License Documentation Impact

Section 5.4.4.1 of the license application will be revised to include the following statement:

“When experimental data from published handbooks are used for mass limits, the following assumptions are applicable to the minimum critical mass; 1) spherical geometry, 2) full water reflection, 3) optimal moderation content, and 4) maximum credible enrichment. In addition, the chemical and physical form specified in the handbook must be at consistent with, or more restrictive than, that which may be present in the actual system to which the limit will be applied.”

NCS-8 Section 5.4.4.3

Provide the following information regarding the use of enrichment as an NCS parameter:

a. Describe how the maximum credible enrichment is determined when controls on enrichment are not used;

b. List the areas where enrichment control is credited for NCS purposes; and

c. Specify the enrichment used in NCS analysis for each node or area where uranium is present.

Section 5.4.4.3 describes the use of enrichment as an NCS parameter. However, since this is an enrichment facility more information is needed to understand how enrichment will be used as an NCS parameter.

Regulations in 10 CFR 70.61(d) require that all nuclear processes be subcritical under both normal and credible abnormal conditions, including use of an approved margin of subcriticality for safety.

GLE Response

Regarding the controlled parameter enrichment, the following applies to the GLE CF license application and ISA Summary:

a. *The maximum credible enrichment is assumed 8.0 wt.% in areas where controls on enrichment are not used. This has been determined to be the maximum credible enrichment for the entire facility.*

b. **Proprietary/Security-Related/Export-Controlled Information has been removed and is withheld from public disclosure per 10 CFR 2.390.**

c. **Proprietary/Security-Related/Export-Controlled Information has been removed and is withheld from public disclosure per 10 CFR 2.390.**

License Documentation Impact

License documentation changes are not required in response to this RAI.

NCS-9 Section 5.4.4.8

Clarify whether or not neutron absorbing materials other than fixed neutron absorbers will be used for NCS purposes.

Section 5.4.4.8 does not clearly indicate that only fixed neutron absorbers will be used for NCS. If other types of absorbers (e.g., boric acid in the cylinder wash) will be used for NCS then the license application should discuss the applicable industry standards.

Regulations in 10 CFR 70.61(d) require that all nuclear processes be subcritical under both normal and credible abnormal conditions, including use of an approved margin of subcriticality for safety.

GLE Response

At the GLE facility only fixed absorbers may be used as NCS controls on neutron absorption. Soluble neutron absorbers (e.g., boric acid) and removable neutron absorbers (e.g., Raschig Rings) are not used as NCS controls. As a result the guidance contained in ANSI/ANS-8.14-2004 “Use of Soluble Neutron Absorbers in Nuclear Facilities Outside Reactors” and ANSI/ANS-8.5-1996(R2002) “Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material” are not applicable to the GLE facility.

License Documentation Impact

Section 5.4.4.8 of the license application will be revised to include the following statement:

“Only fixed absorbers may be used as NCS controls on neutron absorption. Soluble neutron absorbers (e.g., boric acid) and removable neutron absorbers (e.g., Raschig Rings) are not used as NCS controls.”

Chemical Safety (Chapter 6)

CS-1 Section 6.1.6 and Table 6.3

Provide limits for dermal exposure to hydrogen fluoride (HF).

Section 6.1.6 and Table 6.3 address dermal exposures to HF, but do not include specific exposure limits for high consequence and intermediate consequence events. The applicant needs to provide specific exposure limits to implement the performance objectives in 10 CFR 70.61. If specific exposure limits are not proposed, NRC staff will address dermal exposures in a license condition.

The regulations in 10 CFR 70.61(b)(4) and (c)(4) require that the applicant address the risk of credible high and intermediate consequence events for acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material. the regulations in 10 CFR 70.65(b)(7) require an ISA contain a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials that are on-site or expected to be on-site.

GLE Response

GLE will continue to work with the nuclear industry and NRC to develop acceptable exposure limits for HF. If the NRC imposes specific exposure limits in the interim, GLE will comply with those limits.

License Documentation Impact

None at this time.

Fire Safety (Chapter 7)

FS-1 Section 7.1.3

Provide the minimum qualifications relative to fire protection of the facility staff who will assist the GEH Facility Manager in maintaining fire safety.

Section 7.1.3 of the LA states that the GEH Facility Manager ensures that the fire protection program is adequately implemented, but does not describe fire safety staff qualifications.

Regulations in 10 CFR 70.22(a)(6) require that the license application describe the technical qualifications of the staff to engage in the proposed activities.

GLE Response

Chapter 2 of the license application will be revised to establish and describe the Fire Safety Manager position, including staff qualifications. Figure 2-2, GLE Organizational Structure During Operations, will be revised to include the Fire Safety Manager reporting to GLE EHS Manager.

License Documentation Impact

Chapter 2 of the license application will be revised to include Fire Safety Manager position as follows:

> "The Fire Safety Manager is administratively independent of Operations and has the authority to shut down operations when immanent hazardous fire safety conditions are identified. The Fire Safety Manager reports to the GLE EHS Manager and must approve restart of any operation shutdown by the Fire Safety

function. Designated responsibilities of the Fire Safety Manager typically include, but are not limited to, the following:

- Identify fire protection requirements from federal, state, and local regulations which govern GLE Commercial Facility operations;

- Ensure proper implementation of the GLE Fire Protection Program and ensure the performance of the fire protection systems is maintained;

- Management of staff composed of personnel prepared by training and experience in fire protection;

- Management of the GLE CF fire brigade;

- Ensure inspection, testing and maintenance of fire protection systems, features, and equipment is conducted;

- Develop practices regarding fire safety affecting nuclear activities;

- Provide advice and counsel to area managers on matters of fire safety;

- Provide consultation and review of new, existing, or revised equipment, processes, and procedures regarding fire safety; and

- Provide fire safety support for ISAs and configuration control.

The Fire Safety Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and four years of experience in fire protection related assignments. Engineering support staff available to the Fire Safety Manager shall include a licensed fire protection engineer with a minimum of seven years fire protection related experience. Additional available support staff shall include the following disciplines with a minimum of four years fire protection related experience, mechanical engineer, electrical engineer, and structural engineer. Operational support staff performing inspection, observation and training duties shall have a minimum of two years of fire protection experience.

Note: Support staff can be available either through direct employment or under contract."

Section 2.2.7.1 in Chapter 2 of the license application will be revised to include Fire Safety as follows:

"The GLE EHS Manager reports to the GLE Facility Manager. In addition, the GLE EHS Manager has the authority and responsibility to contact the GLE President and CEO with any EHS concerns. The GLE EHS Manager has designated overall responsibility to establish and manage the Licensing, Security and Emergency Preparedness, Material Control and Accounting (MC&A), NCS, Industrial Safety, Environmental Protection, ~~and~~ RP, and Fire Safety Programs to ensure compliance with applicable federal, state, and local regulations and laws."

Section 2.2.7.6 in Chapter 2 of the license application will be revised to remove Fire Safety Functions as follows:

> "The Industrial Safety Manager is administratively independent of Operations and has the authority to shut down operations when potentially hazardous health and safety conditions are identified. The Industrial Safety Manager reports to the GLE EHS Manager and must approve restart of any operation shutdown by the Industrial Safety function. Designated responsibilities of the Industrial Safety Manager typically include, but are not limited to, the following:
>
> - Identify ~~fire protection~~ industrial safety requirements from federal, state, and local regulations which govern GLE Commercial Facility operations;
>
> - Ensure proper implementation of the GLE ~~Fire Protection~~ Industrial Safety Program ~~and maintain the performance of the fire protection systems~~;
>
> - Develop practices regarding non-radiation chemical safety affecting nuclear activities;
>
> - Provide advice and counsel to area managers on matters of industrial safety;
>
> - Provide consultation and review of new, existing, or revised equipment, processes, and procedures regarding industrial safety; and
>
> - Provide industrial safety support for ISAs and configuration control.

The Industrial Safety Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and two years of experience in related assignments; or a high school diploma and eight years of related experience."

FS-2 Section 7.1.3.5

Describe the compensatory fire protection and fire prevention measures to be employed.

Section 7.1.3.5 of the LA addresses control of impairments and lists determinations of needed compensatory fire protection and fire prevention measures as a fire protection impairment procedure. The applicant needs to describe the compensatory fire protection and fire prevention measures that will be used.

The regulations in 10 CFR 70.22(a)(8) require that the license application describe proposed procedures to protect health and to minimize danger to life or property.

<u>**GLE Response**</u>

Typical compensatory measures may include establishment of fire watches, temporary water supply, elimination of potential ignition source, combustible controls, process shutdown, evacuation of impairment area, and temporary construction (of fire barriers).

License Documentation Impact

The last bulleted item in Section 7.1.3.5 of the license application will be revised to include a table of possible impairments and corresponding compensatory measures as follows:

- "Determination of potentially needed compensatory fire protection and fire prevention measures such as those listed in the table below:

Impairment	***Potential Compensatory Fire Protection and Fire Prevention measure***
Sprinkler System Impaired	*Establishment of fire watches* *Elimination of potential ignition sources* *Combustible controls* *Process shutdown* *Evacuation of impairment area* *Mobilization of fire brigade members*
Fire Alarm System Impaired	*Establishment of fire watches* *Elimination of potential ignition sources* *Combustible controls* *Process shutdown* *Evacuation of impairment area* *Mobilization of fire brigade members*
Fire Barrier Impaired (penetration assembly repair or opening protective repair)	*Establishment of fire watches* *Elimination of potential ignition sources* *Combustible controls* *Process shutdown* *Evacuation of impairment area* *Temporary construction (of fire barriers)* *Mobilization of fire brigade members*
Water Supply Impaired	*Temporary water supply*

FS-3 Section 7.3.2

Clarify if the Operations Building is NFPA 220, "Standards on Types of Building Construction," Type I.

As described in Section 7.3.2 of the LA, the Operations Building appears to be NFPA 220 Type I construction. However, it is unclear if the building is a mixture of NFPA 220 Type I and Type II fire resistant designs.

The regulations in 10 CFR 70.22(a)(7) require that the license application describe the proposed equipment and facilities to protect health and minimize danger to life or property.

GLE Response

H3 occupancy fire areas will be Type I (442 or 332) as described in NFPA 220. Other occupancy areas will be Type II.

License Documentation Impact

Both paragraphs in Section 7.3.2 of the license application will be revised for clarity as follows:

"The Operations Building is constructed of noncombustible materials meeting the requirements of ~~Type IA or IB construction as described in Chapter 6 of IBC-2006 The Operations Building is a mixed occupancy of Factory Industrial (F-1) and High Hazard (H-3) as classified by Chapter 3 of IBC-2006 The Operations Building is also designed to limit the potential for contamination and to facilitate decontamination. See GLE LA Chapter 4, Radiation Protection, for additional information regarding radiological controls.~~ NFPA 801, Section 5.5, for fire resistant or noncombustible construction (typically Type I or Type II as defined in NFPA 220, Standard on Types of Building Construction (Ref. 7-14)). The Operations Building also meets the requirements of Type IA or IB construction as described in Chapter 6 of IBC-2006. Type IA construction requires structural frame and the exterior and interior bearing wall elements to meet the requirement of 3-hour fire-rated construction. Type IB construction requires the structural frame and the exterior and interior bearing wall elements to meet the requirements of 2-hour fire-rated construction.

~~Type IA construction requires structural frame and the exterior and interior bearing wall elements to meet the requirement of 3-hour fire-rated construction. Type IB construction requires the structural frame and the exterior and interior bearing walls to meet the requirements of 2-hour fire-rated construction. These construction features meet the requirements of NFPA 801, Section 5.5, for fire resistant or noncombustible construction (typically Type I or Type II as defined in NFPA 220, Standard on Types of Building Construction (Ref. 7-14).~~

In accordance with NFPA 101®, the Operations Building is classified as a Special Purpose Industrial Occupancy, with a hazard classification of ordinary hazard. Additionally, the Operations Building is a mixed occupancy of Factory Industrial (F-1) and High Hazard (H-3) as classified by Chapter 3 of IBC-2006. Fire areas classified as H-3 occupancy are constructed to meet the requirements of Type I (442 or 332) construction as described in NFPA 220. Fire areas classified as F-1 occupancy are constructed to meet the requirements of Type II (222 or 111) construction."

FS-4 Section 7.3.3

Provide the minimum fire resistance of barriers used to separate fire areas and identify if the fire barriers are designated as IROFS in any fire accident scenarios.

Section 7.3.3 of the LA states that fire resistance is commensurate with potential fire severity between the major process areas. However, specific information on the fire resistance of fire barriers and their designation as IROFS is needed.

The regulations in 10 CFR 70.22(a)(7) require that the license application describe the proposed equipment and facilities to protect health and minimize danger to life or property. Regulations in 10 CFR 70.64(b)(1) address in the baseline design criteria the preference for engineered controls over administrative controls.

GLE Response

The minimum fire resistance of fire barriers between fire areas is 2-hours as described in the FHA. The fire resistance of fire barriers within fire areas meets the occupancy separation requirements of IBC (1-hour between sprinklered F-1 and H-3 occupancies, 2-hours between unsprinklered F-1 and H-3 occupancies). The minimum fire resistance of interior and exterior bearing walls is 3-hours. No facility fire barriers are credited as IROFS. Prevention of fires is the primary criteria for the establishment of fire protection IROFS. The combustible controls program is credited as an IROFS to prevent large fires from occurring. Mitigation (fire brigade response) is credited as an IROFS to prevent small fires from spreading. Initial design criteria include noncombustible construction in accordance with NFPA 801 and the IBC. IROFS were selected based on an integrated facility safety methodology of consistency and performance.

License Documentation Impact

Section 7.3.3 of the license application will be revised to include the following description of fire barriers at the end of the second paragraph:

"The minimum fire resistance of fire barriers between fire areas is 2-hours as described in the FHA. The fire resistance of fire barriers within fire areas meets the occupancy separation requirements of IBC (1-hour between sprinklered F-1 and H-3 occupancies, 2-hours between unsprinklered F-1 and H-3 occupancies). The minimum fire resistance of interior and exterior bearing walls is 3-hours."

FS-5 Section 7.3.6

Provide the fire resistance of ductwork used in the ventilation system as described in Section 7.3.6 of the LA. Describe if the fire resistance rating is used only to prevent spread of contamination as a result of fire or fire spread.

Additional information is needed to evaluate the fire safety of the ventilation system ductwork and the impacts of the spread of contamination during fires.

The regulations in 10 CFR 70.22(a)(7) require that the license application describe the proposed equipment and facilities to protect health and minimize danger to life or property.

GLE Response

MCES and HVAC ductwork is constructed of non-combustible material and is designed to meet the requirements of NFPA 801, NFPA 90A, NFPA 90B, NFPA 91, IBC and IMC. HVAC ductwork is not protected by fire rated construction. Openings in rated barriers due to HVAC ducts are protected by fire/smoke dampers or fire dampers of a rating appropriate for the barrier to be protected. Openings in rated barriers due to MCES exhaust ductwork are protected by fire rated construction wrapping or encasing the duct for 10 feet on either side of the rated barrier in accordance with NFPA 91. The rated construction encasing the duct will match the rating of the fire barrier penetrated.

By design, the MCES system is not used to remove unpolished uranium contaminated exhaust gases. Although a slow build up may be expected over the life of the plant, calculations assuming UF_6 dispersion, which bound UO_2F_2 dispersion in a fire, require a material at risk quantity of 40 kg UF_6 before unmitigated release will exceed the performance criteria for worker exposure (and far more is required for public exposure). Based on design and the expected use of the system and on this threshold for exceeding performance criteria, the team conducting the process hazard analysis qualitatively determined that the fire in the ductwork spread low levels of contamination that did not exceed the performance criteria of low severity. Therefore, no IROFS were identified for this event.

License Documentation Impact

The first paragraph in Section 7.3.6 of the license application will be revised as follows:

"The need for effective ventilation both during and immediately following an emergency such as a fire is of considerable importance. The design of the ventilation, confinement, and filtration systems is intended to provide effective ventilation both during and immediately following an emergency such as a fire, and is in accordance with applicable NFPA and/or nationally recognized codes and standards. Where shutdown of the ventilation system is not appropriate, fire/smoke dampers are not required for ventilation duct penetrations. When fire/smoke dampers are not used, an alternative means of protecting against fire propagation is provided. Alternative means of protecting against fire propagation include fire rated construction wrapping or encasing the duct for 10 feet on either side of the rated barrier in accordance with NFPA 91. The rated construction encasing the duct will match the rating of the fire barrier penetrated."

FS-6 Section 7.3.6

Describe the standards used with regard to fire resistance for the high-efficiency particulate air (HEPA) filters and high-efficiency gas adsorption (HEGA) filtration systems.

Section 7.3.6 of the LA discusses HEPA and HEGA filter systems, but does not describe the codes and standards that will be used to address the fire resistance of these filters. The regulations in 10 CFR 70.22(a)(7) require that the license application describe the proposed equipment and facilities to protect health and minimize danger to life or property.

GLE Response

HEPA filters will meet the requirements of UL 900 and UL 586. In addition, the duct work and filter housings of the MCES systems are constructed of noncombustible material. Based on feedback from HEGA manufacturers, there are no nationally recognized standards similar to UL 900 and UL 586 that address fire resistance of HEGA adsorbers. GLE will work with HEGA vendors to identify additional fire protection. The HEGA adsorbers are located downstream of the HEPA filters and by design are not used to trap radionuclides from the process.

License Documentation Impact

The fourth paragraph of Section 7.3.6 of the license application will be revised to include the following statement:

"High-efficiency particulate air (HEPA) filtration systems and/or high-efficiency gas absorption (HEGA) ~~filtration~~ systems are utilized in various areas as part of the confinement function of the ~~HVAC~~ MCES system. HEPA filters will meet the requirements of UL 900, Air Filter Units and UL 586, Standard for High-Efficiency, Particulate, Air Filter Units. The HEPA filters will also meet the spot flame resistance of ASME AG-1, Section FC-5160. When the amount of SNM in a filter exceeds action limits the filter is replaced."

FS-7 Section 7.5.4

Describe the standpipe systems (Class I, II, or III) to be installed in the facility. Describe any employee training that will be conducted in the use of Class II systems, if provided, or if these systems will be for the use of fire brigade personnel only.

Section 7.5.4 of the LA discusses standpipe systems, but does not address the types of standpipe systems to be used or the training provided for their use.

The regulations in 10 CFR 70.22(a)(7) require that the license application describe the proposed equipment and facilities to protect health and minimize danger to life or property.

GLE Response

Standpipe will be Class I. Training will be provided for fire brigade personnel only.

License Documentation Impact

The first sentence in Section 7.5.4 of the license application will be revised as follows:

"Class I standpipe systems installed in accordance with NFPA 14, Standard for the Installation of Standpipe and Hose Systems (Ref. 7-37), are provided in each required exit stairway as required by IBC-2006."

FS-8 Section 7.6.1

Describe the minimum, around-the-clock staffing of the fire brigade.

Section 7.6.1 of the LA describes the on-site fire brigade, but does not address the around-the-clock staffing levels.

The regulations in 10 CFR 70.22(a)(8) require that the license application describe the proposed procedures to protect health and to minimize danger to life or property.

GLE Response

GLE will have around the clock staffing of the fire brigade with a minimum of five fire brigade staff members dedicated to GLE. This is consistent with generic guidance provided in NFPA 1500. GLE will revise this number, as necessary, consistent with development of staffing needs to support the Fire Mitigation IROFS, 5.3100.0(B).

License Documentation Impact

The first paragraph of Section 7.6.1 of the license application will be revised to include the following statement:

"GLE will have around the clock staffing of the fire brigade with a minimum of five fire brigade staff members dedicated to GLE."

Decommissioning

D-1 Section 10.1.1 and Figure 10.1

Provide an alternate schedule for decommissioning and provide justification for the longer schedule if decommissioning is expected to take longer than 24 months.

Section 10.1.1 states, and Figure 10.1 indicates, that decommissioning will take about 3.5 years.

Regulations in 10 CFR 70.38(h) require that decommissioning be completed no later than 24 months following the initiation of decommissioning. Regulations in 10 CFR 70.38(i) allow the Commission to approve a request for an alternate schedule for completion of decommissioning if the alternative is warranted by consideration of 5 factors specified in 70.38(i)(1)-(i)(5).

GLE Response

Decommissioning of the GLE facility will require longer than 24 months, and therefore GLE requests an alternate schedule per 10 CFR 70.38. The reason for the project taking longer than 24 months is due to the complexity and scope of the project, and therefore it is not technically feasible to complete decommissioning within the allotted 24-month period. GLE refers to 10 CFR 70.38(i)(1) allows for this alternate schedule. The schedule proposed in the Decommissioning Funding Plan and Chapter 10 of the License Application took into account two employee shifts per day, and still the schedule calls for greater than 24 months to complete.

License Documentation Impact

Section 10.1.1 of the License Application will be revised as follows:

"10.1.1 Decommissioning Strategy

It is the intent of GLE to decommission the GLE Commercial Facility after facility shutdown to reduce the level of radioactivity remaining in the facility to residual levels acceptable for release of the facility for unrestricted use and for U.S. Nuclear Regulatory

Commission (NRC) license termination pursuant to 10 CFR 20.1401, *General Provisions and Scope (Ref. 10-4)*, and 10 CFR 20.1402, *Radiological Criteria for Unrestricted Use (Ref. 10-5)*. Prior to decommissioning, an assessment of the radiological status of the GLE Commercial Facility will be made. Decommissioning and closure activities will include the cleaning and removal of radioactive and hazardous waste contamination that may be present on materials, equipment, and structures. Decommissioning of the GLE facility will require longer than 24 months, and therefore GLE requests an alternate schedule per 10 CFR 70.38. The reason for the project taking longer than 24 months is due to the complexity and scope of the project, and therefore it is not technically feasible to complete decommissioning within the allotted 24-month period. GLE refers to 10 CFR 70.38(i)(1) allows for this alternate schedule. Overall, decommissioning is estimated to require approximately 3.5 years from facility shutdown to completion of the final status survey of radiological conditions. The GLE decommissioning schedule is presented in Figure 10-1, *Decommissioning Schedule*."

D-2 Section 10.1.2

Eliminate or revise the statements at pages 10-5 and 10-6 to eliminate all ambiguity concerning the sale of salvaged materials assumption.

The introductory paragraph of Section 10.1.2, "Decommissioning Steps," at page 10-5 lists as the fourth decommissioning activity "sales of salvaged materials," and Section 10.1.2.1, "Overview," at page 10-6 states that depleted uranium hexafluoride (UF_6) material, "if not sold or disposed of prior to decommissioning, will either be sold, disposed of by the U.S. Department of Energy, or will be converted to a stable, nonvolatile uranium compound and disposed of in accordance with regulatory requirements." These statements are somewhat misleading, because they suggest that sale of salvaged material is a possible assumption of the decommissioning cost estimate. NRC guidance in NUREG-1757, Volume 3, specifies that the decommissioning cost estimate should not include any credits for the value of salvaged materials. The submission at other points (i.e., page 10-7 and Section 10.1.2.5, "Sale of Salvaged Materials," at page 10-8) makes clear that no credit is taken in the DFP for salvage value.

Regulations in 10 CFR 70.25(a)(1) require that an applicant for a uranium enrichment facility license submit a decommissioning funding plan. Regulations in 10 CFR 40.36(d) and 10 CFR 70.25(e) require that a decommissioning funding plan contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning.

GLE Response

The GLE decommissioning cost estimate did not take into account sale of salvaged material. It was assumed that all material would be disposed of in appropriate disposal facilities.

Licensing Documentation Impacts

The fist paragraph of Section 10.1.2 will be revised as follows:

“Decommissioning activities will generally include: (1) shutdown and purging/draining of process systems; (2) dismantling and removal of equipment; (3) decontamination and destruction of classified material; (4) sales of salvaged materials (note that the potential sale of salvaged materials is not included in the decommissioning cost estimate); (5) disposal of wastes; and (6) completion of a final radiation survey.”…

The seventh bullet in Section 10.1.2.1 will be revised as follows:

“• Depleted UF_6 material, if not sold or disposed of prior to decommissioning, will either be sold, disposed of by the U.S. Department of Energy (DOE), or will be converted to a stable, non-volatile uranium compound and disposed of in accordance with regulatory requirements. Note that the potential sale of depleted UF_6 material is not included in the decommissioning cost estimate, rather the cost of disposal of all materials at appropriate disposal facilities was assumed.”

D-3 Section 10.1.2.7

Provide details of the initial radiation survey, to be performed prior to initial operation.

The initial radiation survey, discussed in Section 10.1.2.7, should be adequate to establish background for use as a reference area for the final survey at decommissioning time. The 7 samples discussed in Environmental Report Sections 3.11.2 are too few and are located outside the enrichment facility proposed site boundary; none are located within the site itself. The following NRC references contain NRC guidance for determining background radiation and selecting background reference areas:

a. “Consolidated Decommissioning Guidance, Volume 2, Characterization, Survey, and Determination of Radiological Criteria,” NUREG-1757, Volume 2, Revision 1, September 2006;

b. “A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys,” NUREG-1505, Revision 1, June 1998, Section 2.2.5;

c. “Multi-Agency Radiation Survey and Site Investigation Manual,” NUREG-1575, Revision 1, August 2000, Section 4.5.

GLE Response

The seven samples mentioned in the Environmental Report Section 3.11.2 are not intended to be the samples used to establish the baseline for decommissioning purposes. As stated in GLE ER Section 6.0, baseline shallow soil uranium concentrations across the 100-acre (40-hectare [ha]) GLE Facility site will be assessed through implementation of a statistically designed sampling program in advance of GLE Facility site preparation and construction. A Sampling and Analysis Plan would be prepared to establish the field and laboratory methods and quality assurance protocol for the assessment. The sampling design to be established in the Plan would be constructed using one or more applicable statistical sampling designs such as:

- *Simple Random Sampling*
- *Systematic and Grid Sampling*

- *Adaptive Cluster Sampling*
- *Composite Sampling.*

This sampling program would also extend to areas outside the 100-acre GLE Facility site where ancillary support structures would be constructed. It is anticipated that the sampling design would result in the collection of a soil sample, on average, for each acre, or possibly smaller subdivisions, of the construction areas.

Either separate to or combined with the soil sampling program described above, GLE would implement a radiological survey across the construction areas that is consistent with the procedures established in the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM; Revision 1, August 2000, and June 2001 updates).

Licensing Documentation Impact

The first paragraph of Section 10.1.7 will be revised as follows:

"A final radiation survey must be performed to verify proper decontamination to allow the site to be released for unrestricted use. The evaluation of the final radiation survey is based in part on an initial radiation survey performed prior to initial operation. The initial survey determines the natural background radiation of the area; therefore, it provides a datum for measurements that determine any increase in levels of radioactivity. GLE will follow the guidance in the following documents to perform the initial survey, which will be performed prior to site preparation and construction:

a. "Consolidated Decommissioning Guidance, Volume 2, Characterization, Survey, and Determination of Radiological Criteria," NUREG-1757, Volume 2, Revision 1, September 2006;

b. "A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys," NUREG-1505, Revision 1, June 1998, Section 2.2.5;

c. "Multi-Agency Radiation Survey and Site Investigation Manual," NUREG-1575, Revision 1, August 2000, Section 4.5."

D-4 Section 10.2.1.2

Clarify that the labor costs are based on the costs that would be incurred by an independent third party conducting the decommissioning activities or explain why the proposed rates are at least equivalent to the costs that would be incurred by an independent third party conducting the decommissioning activities.

NRC guidance in "Consolidated Decommissioning Guidance," NUREG-1757, Volume 3, for developing a site-specific cost estimate for decommissioning specifies that the cost estimate "should assume the work will be performed by an independent third-party contractor." The use of third-party costs will help to ensure that if the licensee is unable or unwilling to perform the decommissioning, sufficient financial assurance will be available so that an independent third-party contractor can be hired to do the work. Any alternative labor cost estimates should have a "clear and reasonable" basis that is provided in the DCE and be at least equivalent to independent third-party costs.

The list of "Major Assumptions" in Section 10.2.1.2 of the submission does not contain any statement that the labor costs are based on the costs that would be incurred by an independent third-party contractor. Table C3.21, "Assumptions," does contain a statement that "Overhead and profit on contractor labor is assumed to be 15%" and that "Craft labor rates were taken from RS Means and professional labor rates provided by GE-Hitachi Nuclear Energy Americas LLC, one of the two immediate parent companies of the applicant, and from EnergySolutions data." Neither statement, however, adequately establishes that all labor costs are based on the assumption that the work will be performed by independent third-party contractors and not direct employees of the applicant or GE-Hitachi Nuclear Energy Americas LLC.

Regulations in 10 CFR 70.25(a)(1) require that an applicant for a uranium enrichment facility license submit a decommissioning funding plan. Regulations in 10 CFR 40.36(d) and 10 CFR 70.25(e) require that a decommissioning funding plan contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning.

GLE Response

As per NUREG-1757, Volume 3, the site-specific cost estimate for decommissioning does assume that an independent third party will do the work and not GE-Hitatchi Nuclear Americas LLC employees. Subsequently, a mark up of 15% to was applied to labor rates to account for third party subcontractor overhead and profit.

License Documentation Impact

The following bullet will be added to Section 10.2.1.2:

"• *An independent third party will do the work and not GLE employees. Thus a mark up of 15% to was applied to labor rates in the decommissioning cost estimate to account for third party subcontractor overhead and profit."*

D-5 Section 10.2.2

Revise to show total decommissioning cost estimate, including the contingency. Section 10.2.2 of the submission at page 10-16 states, "The total estimated cost to dispose of UF_6 tails over the 40-year license, including a six-year ramp up to full capacity and the 25 percent contingency factor, is approximately $2.4 billion." However, this total does not in fact include the contingency. As Table 10-1, "Total Decommissioning Costs," on page 10-21, shows, the total cost of UF_6 tails disposal including 25 percent contingency is $3,034,073,000.

Page 10-16 of the submission should be revised to state the cost as approximately $3.034 billion.

Regulations in 10 CFR 70.25(a)(1) require that an applicant for a uranium enrichment facility license submit a decommissioning funding plan. Regulations in 10 CFR 40.36(d) and 10 CFR 70.25(e) require that a decommissioning funding plan contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning.

GLE Response

GLE will correct the value of the total estimated cost to dispose of UF_6 tails.

Licensing Documentation Impact

The second paragraph of Section 10.2.2 of the license will be modified as follows:

"As with facility decommissioning, the cost estimate will likely change between the time of license issuance and actual decommissioning. GLE commits to adjust the cost estimate for UF_6 tails disposal annually. The method for adjusting the cost estimate will consider the same factors as previously described in Section 10.2.1.3 of this chapter. At full capacity, GLE will generate approximately 10,500 MT of UF_6 tails annually. As with other decommissioning costs, the disposal cost estimate for UF_6 tails disposal is provided in FY 2009 dollars. The total estimated cost to dispose of UF_6 tails over the 40-year license, including a six-year ramp up to full capacity and the 25 percent contingency factor, is approximately $3.0 billion. The basis for this estimate is provided in the DFP. As described in GLE LA Chapter 1, GLE is requesting an appropriate exemption to incrementally fund the disposition of DUF_6 tails. In this manner, financial assurance will be available when needed and will be made available as the decommissioning liability is incurred."

D-6 Section 10.2.3

Delete the emphasized phrase to eliminate any ambiguity suggesting that an external trust might be used.

Section 10.2.3 of the submission at page 10-17 states in its final sentence, "the surety bond will require that the surety company will deposit any funds paid under its terms directly into either an external trust or a standby trust." (Emphasis added). The draft financial assurance instruments submitted by the applicant include an Appendix A containing a "Model Surety Bond" that parallels the model Surety Bond in NUREG-1757, Volume 3, Appendix A. The model surety bond in NUREG-1757 and the model submitted by the applicant both refer only to a standby trust, not an external trust.

GLE Response

GLE will correct Section 10.2.3 to remove the reference to an external trust.

Licensing Documentation Impact

Section 10.2.3 will be revised as follows:

"With respect to the surety bond, GLE presently anticipates providing for the following ttributes: First, a company that is listed as a qualified surety in the Department of Treasury's most recent edition of Circular 570 for the State where the surety was signed with an underwriting limitation greater than or equal to the level of coverage specified in the bond will issue the bond. Second, the bond will be written for a specified term and will be renewable automatically unless the issuer serves notice at least 90 days prior to expiration of intent not to renew. Such notice must be served upon the NRC, the trustee of the ~~external or~~ standby trust, and GLE. Further, in the event GLE is unable to provide an acceptable replacement within 30 days of such notice, the full amount of the bond will be payable automatically, prior to expiration, without proof of forfeiture. The surety bond will require that the surety company will deposit any funds paid under its terms directly into ~~either an external trust or~~ a standby trust."

D-7 Table 10-1

Correct Table 10-1 to provide the correct amount for UF_6 tails disposal.

In Table 10-1, "Total Decommissioning Costs," the entry for UF_6 Tails Disposal is given as "$2,427,25" (*sic.*). Subtracting the amount for 25 percent contingency (UF_6 tails) from the UF_6 Tails Disposal Total suggests that the amount of $2,427,258 should be included in the table for UF_6 tails disposal. Table 10-1 should be corrected to provide the correct amount for UF_6 tails disposal.

GLE Response

The value shown in the table is in error. Table 10-1 will be revised to include the correct value in the line item for UF6 tails disposal.

Licensing Documentation Impact

Table 10-1 will be revised to include the correct value in the line item for UF6 tails disposal.

D-8 Decommissioning Funding Plan, Appendix A

Modify the financial assurance instruments.

The model financial instruments submitted by the applicant generally parallel the model instruments presented in NUREG-1757, Volume 3, Appendix A. The following additions or revisions should be considered by the applicant:

a. Amend the Model Surety Bond included in Appendix A to list the NRC docket number after the NRC license number, as recommended in NUREG-1757;

b. In the Model Surety Bond, in the paragraph beginning, "The Principal and Surety hereby agree to adjust the penal sum of the bond yearly," delete the phrase "provided that the penal sum does not increase by more than 20 percent in any one year." Although this phrase appears in the model surety bond in NUREG-1757, NRC no longer considers it necessary;

c. In Appendix B entitled, "Standby Test Agreement," (emphasis added) modify the submission to label the document as the "Standby Trust Agreement;"

d. In Section 6 (b) of the Model Standby Trust, delete the phrase "such as Government National Mortgage Association, Federal National Mortgage Association, and Federal Home Loan Mortgage bonds and certificates." Although this phrase appears in the model standby trust in NUREG-1757, NRC no longer considers it necessary;

e. In Section 10 of the Model Standby Trust, capitalize “grantor” in the phrase “barring the grantor from asserting any claim or liability against the Trustee. . . ;“ and

f. Revise the Model Specimen Certificate of Resolution to reflect the fact that the applicant is organized as a limited liability company (LLC) and not as a corporation. The Certificate should include the name of the State under whose laws the LLC is organized, replace the word “corporation” with the words “limited liability company,” and, if necessary, replace the words “Board of Directors” and “President” with the word “Manager” or “Managers” or the equivalent titles of the decision-making person or body of persons responsible for the management of GE-Hitachi Global Laser Enrichment, LLC.

Regulations in 10 CFR 70.25(a)(1) require that an applicant for a uranium enrichment facility license submit a decommissioning funding plan. Regulations in 10 CFR 40.36(d) and 10 CFR 70.25(e) require that a decommissioning funding plan contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning.

GLE Response

The Decommissioning Funding Plan will be revised to reflect the appropriate changes, as described below.

Licensing Documentation Impact

a. *The Model Surety Bond in Appendix A will be amended to o list the NRC docket number after the NRC license number, as recommended in NUREG-1757;*
b. *The phrase “*provided that the penal sum does not increase by more than 20 percent in any one year*” will be deleted in In the Model Surety Bond, in the paragraph beginning, “The Principal and Surety hereby agree to adjust the penal sum of the bond yearly,”*
c. *In Appendix B, the title “*Standby Test Agreement*,” will be changed to “*Standby Trust Agreement*;”*
d. *In Section 6 (b) of the Model Standby Trust, the phrase “*such as Government National Mortgage Association, Federal National Mortgage Association, and Federal Home Loan Mortgage bonds and certificates*” will be deleted.*
e. *In Section 10 of the Model Standby Trust, “*grantor*” will be capitalized in the phrase “barring the grantor from asserting any claim or liability against the Trustee. . . ;“ and*
f. *The Model Specimen Certificate of Resolution will be revised to reflect the fact that the applicant is organized as a limited liability company (LLC) and not as a corporation and will include the name of the State under whose laws the LLC is organized.*

Management Measures (Chapter 11)

MM-1 Chapter 11.1

Provide criteria that will be used to evaluate changes to the licensing bases that are not associated with the safety program (i.e., not a management measure, IROFS, or process safety information) or specified in 10 CFR 70.32 to determine whether prior NRC approval is required. Provide information on how this evaluation will be documented and at what frequency will changes be provided to the NRC.

Regulations in 10 CFR 70.72 provide requirements for evaluating whether changes to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel require prior NRC approval before implementation. However, many licensing basis documents are not site, structures, processes, systems, equipment, components, computer programs, or activities of personnel and therefore, changes to these documents cannot be made using the facility change process of 10 CFR 70.72.

Licensees are permitted to make changes to the licensing bases without prior approval as specified by license conditions (10 CFR 70.32). For example, 10 CFR 70.32(i) states that the licensee may change an approved emergency plan without NRC approval, if the change does not decrease the effectiveness of the plan. Similar provisions are included for the safeguards contingency plan (70 CFR 70.32(g)), physical security plan (10 CFR 70.32(e), materials control and accounting plan (10 CFR 70.32(c)(1)(iii)), and plan for physical protection of SNM in transit (10 CFR 70.32(d)).

An applicant or licensee may propose a license condition to allow other licensing bases changes without prior NRC approval. License conditions of this type should contain the following:

1. Criteria for preapproval;
2. Commitment to document the licensee's evaluation supporting the findings that preapproval is not required; and
3. Reporting frequency for providing changes to the NRC after implementation.

GLE Response

GLE requests authorization to make changes to the License Application, as described below, for changes that do not decrease the effectiveness of commitments.

License Documentation Impact

Section 1.2.5.5 will be added to the License Application as follows:

"1.2.5.5 Authorization to Make Changes to License Commitments

Changes Requiring Prior Approval

GLE shall not make changes to the License Application that decrease the effectiveness of commitments, without prior NRC approval. For these changes, GLE will submit to the NRC, for review and approval, an application to amend the license. Such changes will not be implemented until approval is granted.

Changes Not Requiring Prior Approval

Upon documented completion of a change request for a facility or process, GLE may make changes in the facility or process as presented in the License Application, or conduct test or activities not presented in the License Application, without prior NRC approval, subject to the following conditions:

1 There is no degradation in the safety commitments in the License Application
2 The change, test, or activity does not conflict with any condition specifically stated in the License.

Records of such changes shall be maintained, including technical justification and management approval, in dedicated records to enable NRC inspection upon request at the facility. A report containing a description of each such change, and appropriate revised sections to the License Application, shall be submitted to the NRC within three months of implementing the change."

MM-2 Section 11.1.2

Provide a definitive statement as to what is meant by the phrase "maintained current as IROFS." Provide information on the applicant's plans to use "IROFS Boundary Packages" to organize and control information related to each IROFS.

Section 11.1.2, "Design Requirements," states that IROFS identified in the ISA Summary and design documents are maintained current as IROFS and are identified in more detail during the final design.

The license application needs to specifically define the phrase "maintained current as IROFS" in sufficient detail to understand its function in relation to the performance requirements of 10 CFR 70.61. "IROFS Boundary Packages" should be considered to organizing and updating information on IROFS.

Regulations in 10 CFR 70.62(d) require that management measures shall be established to ensure compliance with the performance requirements of 10 CFR 70.61. The management measures shall ensure that engineered and administrative controls and control systems that are identified as IROFS are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their function when needed, to comply with the performance requirements of 10 CFR 70.61.

GLE Response

The phrase "maintained current as IROFS" used in Section 11.1.2 is a typographical error and has no meaning.

GLE intends to use a procedure for "IROFS Boundary Packages" to organize and update information on IROFS. An example of the "IROFS Boundary Package" procedure will be provided for information by March 30, 2010.

License Documentation Impact

The third sentence in last paragraph in Section 11.1.2 of the license application will be revised as follows:

"IROFS identified in the ISA Summary and design documents are identified in more detail during the final design."

MM-3 Sections 11.4.1 and 11.8.2

Describe how the "stop work" provision applies to the accomplishment of work as specified in procedures other than implementing QA procedures (i.e., operating procedures/instructions).

Section 11.4.1 of the license application describes two categories of procedures: management control procedures (which include QA procedures) and operating procedures/instructions. Section 11.8.2 of the license application states that when work cannot be accomplished as specified in implementing QA procedures, work is stopped until corrective action is taken.

Procedures are a functional element of management measures as defined in 10 CFR 70.4. The regulations in 10 CFR 70.62(d) require that management measures ensure that engineered and administrative controls and control systems that are identified as IROFS are implemented and maintained to ensure they are available and reliable to perform their function when needed.

GLE Response

GLE will insert a paragraph in Section 11.4.1 that addresses stop work in regards to all GLE procedures as opposed to only QA procedures.

License Documentation Impact

License Application, Section 11.4.1 will be revised to include the following paragraph:

"Compliance with GLE procedures is mandatory. If any aspect of a procedure is unclear or incorrect as written, personnel shall safely stop the operation and/or activity and contact management. The operation and/or activity shall not restart until corrective action has been taken. If a situation is not defined in the procedure content or an unexpected response is obtained, management notification is also required. Deviations from operating procedures and unforeseen alternations in process conditions that affect nuclear criticality safety shall be reported to management, investigated promptly, corrected as appropriate, and documented."

MM-4 Section 11.5

Provide information on whether independent assessments of safety program elements will be conducted by offsite groups or individuals not involved in licensed activities.

Audits and assessments are one of the eight functional elements of management measures as defined in 10 CFR 70.4.

Regulations in 10 CFR 70.62(d) require that management measures ensure that engineered and administrative controls and control systems that are identified as IROFS are implemented and maintained to ensure they are available and reliable to perform their function when needed.

GLE Response

Individuals not involved in the area being assessed will conduct independent assessments. These assessments may include on-site or off-site individuals.

License Documentation Impact

A sentence following the first sentence will be added to Section 11.1.5:

"Individuals not involved in the area being assessed will conduct independent assessments."

MM-5 Section 11.7

Describe procedures to promptly detect and correct any deficiencies in the records management system or its implementation.

Section 11.7 does not discuss the detection and correction of deficiencies in the records management system or its implementation.

The regulations in 10 CFR 70.62(a)(2) state that each licensee or applicant shall establish and maintain records that demonstrate compliance with the requirements for process safety information, integrated safety analysis, and management measures. In addition, records management is a functional element of management measures and 10 CFR 70.62(d) requires that management measures ensure that engineered and administrative controls and control systems that are identified as IROFS are implemented and maintained to ensure they are available and reliable to perform their function when needed.

GLE Response

The Records Management System is subject to annual assessments as defined in GLE License Application, Section 11.5.2, Scheduling of Audits and Assessments. Corrections to records are reviewed and approved by the originating organization. The corrections include the date and the identification of the individual authorized to issue the correction. Replacement, restoration, or substitution of lost or damaged records is performed in accordance with implementing procedures. These procedures provide for appropriate review and approval by the originating organization and any additional information associated with the replacement.

License Documentation Impact

NEDE-33451, Quality Assurance Program Description, Chapter 18 will be revised to include the response above.

MM-6 Chapter 11.7

Provide criteria that will be used to determine which records must have controlled access.

Section 11.7 does not discuss the criteria for determining which records must have controlled access.

Records management is a functional element of management measures as defined in 10 CFR 70.4. 10 CFR 70.62(d) requires that management measures ensure that engineered and administrative controls and control systems that are identified as IROFS are implemented and maintained to ensure they are available and reliable to perform their function when needed.

GLE Response

Records classified as lifetime records are access controlled in the GLE Records Center. Records classified as nonpermanent records are controlled by the responsible organization until they are no longer useful.

The GLE Records Center shall be access controlled and a list shall be maintained designating personnel with permitted access to the records. The Records Center shall not be left unattended unless it is properly secured. Access to the Records Center shall be formally requested and approved by the supervisor responsible for records management.

License Documentation Impact

NEDE-33451, Quality Assurance Program Description, Chapter 18 will be revised to include the information above.

MM-7 Section 11.8.2

Review the definition of commercial grade item for Part 70 licensees as stated in 10 CFR 21.3 and determine whether an exemption is needed to procure certain unique components associated with uranium enrichment. Provide information on whether the applicant considers IROFS to be basic components as defined in 10 CFR 21.3.

Regulations in 10 CFR 21.3 authorize the use of a commercial grade dedication program for nuclear power plants. Other non-reactor licensees have been granted exemptions to procure unique components. See NRC's letter to Louisiana Energy Services, dated February 11, 2009 (ML083400454).

GLE Response

The definitions stated in 10 CFR 21.3 of basic components, commercial-grade items, critical characteristics, dedication, and dedicating entity as they apply to a facility licensed pursuant to 10 CFR 70 were reviewed along with the NRC letter to Louisiana Energy Services referenced in the RAI. These reviews coupled with the basic design of the GLE Commercial Facility determined that an exemption will be necessary to procure certain unique components for use as IROFS (i.e., basic components).

GLE will include as Chapter 1, Paragraph 1.2.5.5, of the License Application an exemption from 10 CFR 21.3 regarding the definitions of basic components, commercial-grade items, critical characteristics, dedication, and dedicating entity.

License Documentation Impact

The License Application, Chapter 1, will be revised to add the following as Paragraph 1.2.5.5:

1.2.5.5 Exemption from 10 CFR 21, § 21.3 Definitions

GLE requests authorization to replace the definitions of basic component, commercial-grade items, critical characteristics, dedication, and dedicating entity as they apply to facilities licensed pursuant to 10 CFR 70 with the following:

Basic Component: A basic component means a structure, system, or component designated as an item relied on for safety (IROFS), or part thereof that affects the IROFS function, that is directly procured by the licensee of a facility or activity subject to the regulations in Part 70 and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission would create a substantial safety hazard (i.e., exceed the performance requirements of 10 CFR 70.61). In all cases, basic components include IROFS-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, whether these services are performed by the component supplier or others.

Commercial-grade item: A commercial-grade item means a structure, system, or component, or part thereof that affects its IROFS function that was not designed and manufactured as a basic component. Commercial-grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defect or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

Critical characteristics: Critical characteristics are those important design, material, and performance characteristics of a commercial-grade item that, once verified, will provide reasonable assurance that the item will perform its intended IROFS function.

Dedication: Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended IROFS function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR 50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix

B. The process is considered complete when the item is designated for use as a basic component.

Dedicating entity: Dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to Section 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process. In cases where the Licensee applies the commercial grade item procurement strategy and performs the dedication process, the Licensee would assume full responsibility as the dedicating entity."

The NRC approved a similar exemption from another non-reactor licensee in its letter to Louisiana Energy Services, dated February 11, 2009 (ML083400454).

In addition, NEDE-33451, Quality Assurance Program Description, will be revised to incorporate the information above.

MM-8 Section 11.8.2

Explain how the following factors are considered in determining an IROFS' contribution to risk reduction:

1. Degree to which functional compliance can be demonstrated by test, inspection, or maintenance methods;
2. Anticipated lifespan;
3. Importance of data generated; and
4. Reproducibility of results.

Section 11.8.2.2 of the license application describes factors that are considered in implementing a graded QA approach.

The regulations in 10 CFR 70.62(d) state that measures applied to all IROFS may be graded commensurate with the reduction in risk attributable to that IROFS.

GLE Response

Based on the two phone conversations about this item, GLE has reevaluated the presentation of the concept of "graded approach" that we intend to apply and how these sections communicate that approach. As presented, the QAPD does not differentiate substantial differences between QL-1 and QL-2 treatment, and currently GLE has not declared any sole IROFS that qualify as QL-1. From a philosophical standpoint, the difference between treatment of a QL-1 and QL-2 IROFS would be in the application of management measures to assure that the sole IROFS maintained reliability with a failure frequency of 10^{-5} per year, or less. As a result, GLE will remove the terminology of "graded approach" from this section. Since the types of IROFS expected to be encountered are diverse, consisting of four basic types of IROFS, and the various *attributes that each type of IROFS must emphasize to perform its safety function are often quite different, GLE intends to apply the appropriate rigor for each management measure as discussed below.*

Configuration Management:

GLE intends the elements of configuration management, specifically, CM policy, design requirements, document control, change control, and application of assessments, to be applied the same for the QL-1 and QL-2 level IROFS (there are no QL-3 level IROFS by definition).

Maintenance

GLE expects that the application of the types of maintenance (corrective, including calibration, preventative, surveillance and monitoring, and functions testing) and the frequencies of this maintenance will be highly dependent on the type of IROFS, the specific components within the IROFS boundary, the historical failure frequency associated with the components or with the human elements of performance, and the reliability required of the IROFS. Therefore, GLE expects that the application of maintenance attributes to be chosen using information obtained by evaluating the nine areas of consideration presented in Section 11.8.2.2 (not all of which apply to each type of IROFS).

Training and Qualifications

GLE intends that a certain minimum training be required for all workers working with or in the vicinity of hazardous operations that are governed by IROFS. This is spelled out in Section 11.3 and would be performed for areas where QL-1 and QL-2 IROFS are involved to protect aspects of the work area.

GLE expects that the specific application of training and qualifications, consistent with the general descriptions provided in Section 11.3, will be driven by a task analysis that addresses human factors elements, complexity of the safety function carried out, and basic knowledge of the individuals involved. Based on the task analysis, appropriate training will be developed utilizing classroom, performance-based on-the-job, testing, etc. commensurate with the nine areas of consideration presented in Section 11.8.2.2 (not all of which apply to each type of IROFS). This is a standard element of a systematic approach to training.

Procedures

GLE intends that all activities associated with the operation of IROFS will be governed by procedures associated with all aspects of the task. All procedures involving implementation of IROFS would be controlled according to the CM program to assure proper, accurate, valid procedures are used regardless of quality level.

However, GLE recognizes that some complex activities (depending on the IROFS type and nature) will require procedures that have higher levels of human factors elements incorporated in their use (such as in-hand use, step-by-step check-offs, two-person verification of action confirmation, etc.). The amount of rigor applied to each task will be based on the task analysis to determine the application level of detail needed in *the procedure and the appropriate usage policies. These decisions would use information identified by the nine areas of consideration, as applicable, presented in Section 11.8.2.2.*

Audits and Assessments

GLE intends to apply a basic level of audits and assessments to all IROFS (QL-1 and QL-2). However, as identified in Section 11.8.18, the frequencies are commensurate with the status and importance of the activity, and again, the nine areas of consideration presented in Section 11.8.2.2 would be used in developing these frequencies.

Incident Investigations

GLE intends that incidents associated with IROFS implementation be investigated and resolved with the same approach regardless of quality level.

Records Management

GLE intents that all records for activities associated with IROFS implementation be managed with the same approach regardless of quality level.

Other Quality Assurance Elements

The various Quality Assurance Elements dovetail with one or more of the management measures presented above. Under Design Control, Procurement Control, Document Control, Control of Purchased Items and Services, Identification and Control of Materials, Parts, and Components, Control of Measuring and Test Equipment, Handling Storage and Shipping Controls, Control of Nonconforming Items, Corrective Action, and Quality Assurance Records, there are no distinctions within the program with respect to QL-1 and QL-2 level IROFS. As addressed above in the discussions of management measures and as indicative of the type of QA program element, the development of attributes for the Instructions, Procedures, and Drawings, Control of Special Processes, Inspections, Test Control, Inspection Test and Operating Status, and Assessments and Audits QA elements may be applied with some varying degree of rigor commensurate with the type of IROFS, and again, using the nine areas of consideration presented in Section 11.8.2.2.

GLE commits to identifying the results of determining the attributes of management measures and QA Program elements applicable to each IROFS in the IROFS Boundary Definitions Package as those attributes are defined and justified during design. GLE also commits that the IROFS Boundary Definitions Packages will be developed and managed under the CM elements of the QA program.

License Documentation Impact

Section 11.8.2.2 will be revised to read as:

"11.8.2.1 QA Level 1

QA Level 1 (QL-1) is applied to single IROFS (sole IROFS) preventing or mitigating a high consequence event. Management measures are applied to each QL-1 IROFS consistent with the type of IROFS to assure that the IROFS remains reliable at its credited failure frequency when called upon to be available. Also, all applicable QA Program requirements are applied to QL-1 IROFS in a manner necessary to achieve this goal."

11.8.2.2 QA Level 2

QA Level 2 (QL-2) is applied where two or more IROFS are credited to prevent or mitigate a high consequence event, or where any single IROFS (sole IROFS) prevents~~ing~~ or mitigates~~ing~~ an intermediate consequence event. Management measures are applied to QL-2 IROFS consistent with the type of IROFS to assure that the IROFS remains reliable at its credited failure frequency when called upon to be available. All applicable QA Program requirements are also applied to QL-2 IROFS ~~using a graded approach~~in a manner necessary to achieve this goal.

The extent that attributes of management measures and QA program elements are applied to QL-1 and QL-2 IROFS will be determined by evaluating the factors that contribute to reliability of each IROFS. The management measure and QA element attributes for those aspects of the activity that influence reliability of the IROFS will be determined by evaluating the design, function, and task analyses associated with operating and maintaining the IROFS and by assigning the characteristic to the attribute ~~graded approach is implemented through approved written procedures~~ taking into consideration the following:

- Risk significance,
- Applicable regulations, industry codes, and standards,
- Complexity or uniqueness of an item/activity and the environment in which it has to function,
- Quality history of the item in service or activity,
- Degree to which functional compliance can be demonstrated or assessed by test, inspection, or maintenance methods,
- Anticipated life span,
- Degree of standardization,
- Importance of data generated, and
- Reproducibility of results.

The management measure and QA elements attributes assigned to each IROFS will be approved through the configuration management process associated with ISA Baseline Documents and specifically through approval of the IROFS Boundary Definition Packages as the design matures, procedures and training are developed, and pre-operational readiness reviews are conducted."

MM-9 Section 11.8.2

Describe the extent to which management measures, including the QA program requirements, will be applied to QL-1, QL-2, and QL-3 IROFS to ensure they are available and reliable to perform their safety function as required by 10 CFR 70.62(d).

Section 11.8.2 does not discuss how management measures will be applied to QL-1, QL-2, and QL-3 IROFS.

The regulations in 10 CFR 70.62(d) require that management measures ensure that engineered and administrative controls and control systems that are identified as IROFS are implemented and maintained to ensure they are available and reliable to perform their function when needed. The application of measures may be graded commensurate with the reduction of risk attributable to the IROFS.

<u>GLE Response</u>

Section 11.8.2.3 incorrectly states that QL-3 applies to "safety controls," which implies that an IROFS can be categorized as QL-3. As stated in Sections 11.8.2.1 and 11.8.2.2, all IROFS fall within either the QL-1 or QL-2 category; QL-3 cannot be used in connection with an IROFS.

Section 11.8.2.1, as stated, implies that only the "QA Program requirements are applied to QL-1 IROFS." All management measures including QA program requirements are applied to QL-1 IROFS.

Section 11.8.2.2 addresses QL-2 IROFS. Like Section 11.8.2.1, this section also implies that only the "QA Program requirements are applied to QL-2 IROFS." All management measures including QA program requirements are applied to QL-2 IROFS.

<u>License Documentation Impact</u>

Sections 11.8.2.1, 11.8.2.2, and 11.8.2.3 will be revised to read as follows:

> [11.8.2.1] "QA Level 1 (QL-1) is applied to single IROFS (sole IROFS) preventing or mitigating a high consequence event. All management measures and QA Program requirements are applied to QL-1 IROFS."
> [11.8.2.2] "QA Level 2 (QL-2) is applied where two or more IROFS are credited to prevent or mitigate a high consequence event, or any single IROFS (sole IROFS) preventing or mitigating an intermediate consequence event. Management measures and QA Program requirements are applied to QL-2 IROFS using a graded approach. The graded approach is implemented through approved written procedures taking into consideration the following:"
> [11.8.2.3] "QA Level 3 (QL-3) ~~covers safety controls~~is applied to items that are neither~~not~~ QL-1 nor QL-2. QL-3 items (not IROFS) are controlled in accordance with standard commercial practice and do not require application of management measures~~the maintenance of quality records~~."

MM-10 Section 11.8.2

Explain how records of QL-3 IROFS will be maintained to meet the records requirements of 10 CFR 70.72(f), 10 CFR 70.62(2) and (3), and 10 CFR 21.51.

Records management is a functional element of management measures as defined in 10 CFR 70.4. However, there is no discussion of how records will be maintained for QL-3 IROFS.

The regulations in 10 CFR 70.62(d) require that management measures ensure that engineered and administrative controls and control systems that are identified as IROFS are implemented and maintained to ensure they are available and reliable to perform their function when needed.

GLE Response

Section 11.8.2.3 incorrectly states that QL-3 applies to "safety controls," which implies that an IROFS can be categorized as QL-3. As explained in the response to RAI MM-9, all IROFS fall within the QL-1 and QL-2 categories, and a QL-3 item may not be an IROFS. IROFS are subject to management measures; QL-3 items are not.

License Documentation Impact

Refer to the response to RAI MM-9 for the documentation impact.

MM-11 Section 11.8.2

Describe how the Quality Assurance Program Description (QAPD) applies to QL-3 IROFS.

The QAPD states that application of the program is mandatory for IROFS and describes requirements applicable to QL-1 and QL-2 IROFS.

Other QA elements, such as the QA program, are management measures as defined in 10 CFR 70.4. The regulations in 10 CFR 70.62(d) require that management measures ensure that engineered and administrative controls and control systems that are identified as IROFS are implemented and maintained to ensure they are available and reliable to perform their function when needed.

GLE Response

Refer to the responses to RAI MM-9 and -10.

As explained in the responses to RAI MM-9 and -10, all IROFS fall within the QL-1 or QL-2 category. Section 3 of the QAPD does not specifically state that it is not applicable to QL-3 items, it only states that QL-3 items do not require quality assurance records.

In parallel with the license document changes indicated in the response to IRA MM-9, GLE commits to revising Section 3 of the QAPD to incorporate parallel language regarding QL-3.

License Documentation Impact

Refer to the response to RAI MM-9 for the documentation impact.

MM-12 Section 11.8.2

Confirm that the requirements of Part 21 will be followed. Additionally, describe how the dedication process for basic components (QL-1, QL-2, and QL-3 IROFS) procured commercially will meet the requirements of this part.

The regulations in 10 CFR 21 are not referenced in the license application.

GLE Response

The requirements of Part 21 will be followed. In the following paragraphs, the terms "basic component," "commercial-grade item," "dedication," etc. are those provided in the response to RAI MM-7, which addresses the definitions or terms applicable to dedication of commercial-grade items.

Dedication Process

Whenever possible, basic components (i.e., IROFS or parts thereof) will be procured from suppliers that possess and implement a quality assurance program meeting the requirements of 10 CFR 50, Appendix B and that have been evaluated and placed on an approved suppliers list. If an IROFS or part thereof cannot be procured as a basic component due to the applicable supplier not possessing an approved QA program, then GLE will formally dedicate a commercial-grade item for use as or in an IROFS (basic component).

Dedication of commercial-grade items will be implemented through application of the QAPD (NEDE-33451) and approved, flow-down procedures. Those procedures will define the processes for determining critical characteristics and confirming the critical characteristics acceptability by special inspection and test along with, as necessary, one or more of the supplemental activities stated in the definition of "dedication."

QL-1, QL-2, and QL-3 Applicability to IROFS

As discussed in the response to RAI MM-9, all IROFS fall within the QL-1 and QL-2 categories, and a QL-3 item may not be designated for use as an IROFS or part thereof. As necessary, the commercial-grade item dedication process discussed above will be applied to items procured commercially and intended for use as IROFS.

License Documentation Impact

GLE will revise the LA, Chapter 11, Section 11.8, Other Quality Assurance Elements, as follows:

> "GLE has developed a QA Program that applies to the design, construction, operation, and decommissioning of the GLE Commercial Facility. Application of the QA Program is mandatory for items (SSCs, equipment, and activities) identified as IROFS in accordance with 10 CFR 70.4, Definitions (Ref. 11-12), 10 CFR 70.61, Performance Requirements (Ref. 11-13), ~~and~~ 10 CFR 70.64 (Ref. 11-2), and 10 CFR 21 (Ref. 11-XX). The QA Program, in conjunction with the other management measures, ensures IROFS will be available and reliable to perform the required safety functions when needed."

GLE will revise the LA, Chapter 11, Section 11.8.4, Procurement Control, to add the following as the third paragraph:

"In accordance with 10 CFR 21, Reporting of Defects and Noncompliance, the procurement process procedures include requirements that GLE confirm each supplier/vendor approved to provide basic components has an approved process in place that implements the requirements of Part 21. In cases where commercial-grade items are to be procured and then dedicated for use as IROFS or parts thereof, the procurement process procedures include requirements that GLE define to the supplier those elements of the supplier's process controls that are mandatory and any other requirements necessary to assure critical characteristics will be met."