BASIC COMPONENT DEFINITION FOR THE HERMES NON-POWER TEST REACTORS

1 BACKGROUND

Kairos Power is implementing a vertically integrated strategy to design, license, manufacture, and operate the Hermes test reactors. This strategy is unique in that Kairos Power will be the designer of the Hermes facility, the manufacturer of most safety-related components for the Hermes facility, and the licensee/operator of the Hermes facility. These design and manufacturing activities completed by Kairos Power will not be subject to contractual requirements in procurement documents with the licensee, because Kairos Power is the licensee for Hermes.

10 CFR Part 21 and 10 CFR 50.55(e) contain requirements to notify the Commission of both failures to comply and defects related to substantial safety hazards. The regulations establish definitions of the terms that are necessary to understand and implement the notification requirements for facilities other than power reactors that differ from the definitions used for power reactor facilities.

Since Kairos Power is implementing a unique strategy, it is necessary to establish a regulatory position explaining how the definitions of these terms and the notification requirements contained in 10 CFR Part 21 and 10 CFR 50.55(e) specifically apply to the Hermes test reactor facility.

2 REGULATIONS AND GUIDANCE

The definitions of "Basic Component," "Defect," "Deviation," and "Procurement Document" are provided in two places in regulations. The 10 CFR Part 21 definitions are provided in 10 CFR 21.3, and the 10 CFR 50.55(e) definitions are provided in 10 CFR 50.2. The portions of these definitions that are applicable to facilities other than power reactors are provided below:

Basic Component:

10 CFR 21.3	10 CFR 50.2
(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license	(2) When applied to other types of facilities or portions of such facilities for which construction permits are issued under § 50.23, a component, structure, system or part thereof that is directly procured by the construction permit holder for the facility subject to the regulations of this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

10 CFR 21.3	10 CFR 50.2
issued by the Commission could create a substantial safety hazard.	
(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.	(3) In all cases, basic component includes safety related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware, whether these services are performed by the component supplier or other supplier.

Defect:

10 CFR 21.3	10 CFR 50.2
(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard;	(1) A deviation in a basic component delivered to a purchaser for use in a facility or activity subject to a construction permit under this part, if on the basis of an evaluation, the deviation could create a substantial safety hazard; or
(2) The installation, use, or operation of a basic component containing a defect as defined in this section;	(2) The installation, use, or operation of a basic component containing, a defect as defined in paragraph (1) of this definition; or
(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of part 50 or part 52 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;	(3) A deviation in a portion of a facility subject to the construction permit of this part provided the deviation could, on the basis of an evaluation, create a substantial safety hazard.
(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 or part 52 of this chapter;	

Deviation:

10 CFR 21.3	10 CFR 50.2
a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.	a departure from the technical or quality assurance requirements defined in procurement documents, safety analysis report, construction permit, or other documents provided for basic components installed in a facility subject to the regulations of this part.

Procurement Document:

The 10 CFR 21.3 definition of "Procurement Document" is the same as the 10 CFR 50.2 definition of "Procurement Document." Both definitions are given below.

10 CFR 21.3	10 CFR 50.2
a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.	a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Supplying or Supplies:

The definition of "Supplying or supplies" provided in 10 CFR 21.3 is described below. There is no corresponding definition provided in 10 CFR 50.2.

10 CFR 21.3	10 CFR 50.2
Supplying or supplies means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.	

Requirements to report failures to comply and defects to the Commission are contained in both 10 CFR 21.21(d)(1) and 10 CFR 50.55(e)(4). The reporting requirements applicable to facilities other than power reactors are provided below.

Reporting Requirements:

10 CFR 21.21(d)(1)	10 CFR 50.55(e)(4)
A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting --	(i) The holder of a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license who obtains information reasonably indicating that the facility fails to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director or responsible officer or designated person as discussed in paragraph (e)(4)(v) of this section.
(i) The manufacture, construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or	(ii) The holder of a facility construction permit subject to this part, combined license, or manufacturing license, who obtains information reasonably indicating the existence of any defect found in the construction or manufacture, or any defect found in the final design of a facility as approved and released for construction or manufacture, must notify the Commission of the defect through a director or responsible officer or designated person as discussed in paragraph (e)(4)(v) of this section.
(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing, design certification, or approval requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.	

Applicable Federal Register Notices for 10 CFR Part 21:

- Federal Register, Volume 40, No. 42, pages 8832 through 8834, March 3, 1975
- Federal Register, Volume 42, No. 108, pages 28891 through 28896, June 6, 1977
- Federal Register, Volume 42, No. 137, page 36803, July 18, 1977

- Federal Register, Volume 43, No. 203, pages 48621 through 48622, October 19, 1978
- Federal Register, Volume 53, No. 214, pages 44594 through 44602, November 4, 1988
- Federal Register, Volume 56, No. 147, pages 36081 through 36092, July 31, 1991

Applicable Federal Register Notices for 10 CFR 50.55(e):

- Federal Register, Volume 37, No. 62, pages 6459 to 6461, March 30, 1972
- Federal Register, Volume 53, No. 214, pages 44594 through 44602, November 4, 1988
- Federal Register, Volume 56, No. 147, pages 36081 through 36092, July 31, 1991

Regulatory Guidance Documents

- NUREG-0302, Revision 1, Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance, July 12-26, 1977.

3 REGULATORY ANALYSIS

This regulatory analysis will focus on the application of the definitions of "Basic Component," "Defect," "Deviation," "Procurement Document," and "Supplying/Supplies" as they apply to facilities other than power reactors and the notification requirements for facilities other than power reactors that rely on these definitions in accordance with 10 CFR Part 21 and 10 CFR 50.55(e).

3.1 Application of Definition of Basic Component to Facilities Other Than Power Reactors

As defined in 10 CFR 21.3, basic components for facilities other than power reactors include:

- Structures, systems, components, or parts thereof, that:
  - affect a safety function,
  - are directly procured by the licensee of a facility, and
  - in which a defect or failure to comply could create a substantial safety hazard.
- Safety-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.

As defined in 10 CFR 50.2, basic components for facilities other than power reactors include:

- Structures, systems, components, or part thereof that:
  - are directly procured by the construction permit holder for the facility and
  - in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

- Safety-related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware, whether these services are performed by the component supplier or other supplier.

10 CFR Part 21 was initially published for public comment in Federal Register notice 40 FR 8832 on March 3, 1975. The original draft regulation defined a basic component as "any component, structure, system or constituent part thereof, supplied for or utilized in a facility or activity subject to the licensing requirements of Parts 30, 40, 50, 70, or 71 of this chapter in which a defect or failure to comply with any applicable regulation in this chapter, order or license issued by the Commission could create a substantial safety hazard."

The final Part 21 regulation was published in Federal Register notice 42 FR 28892 (June 6, 1977). Supplemental information provided with this notice clarified that Part 21 applies to organizations that directly supply the licensee of a facility other than a nuclear power reactor. This contrasts with the statement contained in the supplemental information, which explains that Part 21 applies to organizations that may be many procurement tiers away from the holder of a license to construct or operate a nuclear power reactor.

This Federal Register notice also describes changes to the original draft of Part 21 as published on March 3, 1975 that were made largely based on consideration of public comments. The changes related to this regulatory position paper are evaluated below:

- Change (3) discusses that the definition of "defect" as applied to components themselves has been restricted to include those deviations in delivered components from technical requirements included in the procurement documents that could create a substantial safety hazard. It further states that "defect" also includes a deviation in a portion of the facility subject to the construction permit or manufacturing licensing requirement of Part 50 provided the deviation could create a substantial safety hazard AND the portion of the facility containing the deviation has been offered to the purchaser for acceptance. Defect also includes for facilities licensed under Part 50, any condition or circumstance involving a basic component that could contribute to exceeding a safety limit set forth in the Operating License Technical Specifications. Procurement documents, as referenced in the clarified definition of "defect," means a contract that defines the requirements that facilities or basic components must meet in order to be considered acceptable by the purchaser. For facilities other than nuclear power plants, this change focuses all definitions of "defect" on items that have been delivered or offered for acceptance to a purchaser that deviate from requirements in procurement documents.

- Change (4) describes that the definition of basic component was divided into two parts with the definition applicable to power reactors based on guidance in Regulatory Guide 1.29 and the definition for other facilities and activities being components that are directly procured by a licensee. The original definition in the draft rule of basic component was "any component, structure, system or constituent part thereof, supplied for or utilized in a facility or activity subject to the licensing requirements of Parts 30, 40, 50, 70, or 71 of this chapter

in which a defect or failure to comply with any applicable regulation in this chapter, order or license issued by the Commission could create a substantial safety hazard." The change incorporated into the final rule removed "supplied for or utilized in the facility" from the definition of basic component. By replacing "supplied for or utilized in the facility" with "directly procured" in the definition of basic component for facilities other than power reactors, components that are manufactured or fabricated by the licensee do not meet the definition of basic components because they are not directly procured by the licensee from a supplier. This differs from the population of basic components for nuclear power reactors that aligns with the definition Seismic Class 1 from Regulatory Guide 1.29, and does not include the requirement that the component also be directly procured.

- Change (6) describes that clarification was added regarding which organizations are subject to the regulations. This includes not only licensees and organizations that physically construct facilities and physically supply components, but also organizations that only supply safety-related services in order to bring within the regulation the various organizations that can create a substantial safety hazard. It includes an example of a basic component fabricated by one organization using a design from another organization. The example states that the possibility to create a substantial safety hazard based upon a faulty design exists upon delivery of the design that fails to comply or contains a defect. It further states that a substantial safety hazard based upon faulty fabrication exists upon delivery of the item that fails to comply or contains a defect. Based on the clarification that Part 21 applies to organizations that directly supply facilities other than power reactors and the change in definition of basic component described above, to apply this example directly to a facility other than a power reactor, it must be assumed that both the design organization and the fabrication organization directly supply their services to the licensee. In this case, a defect or failure to comply could exist upon delivery of a faulty design to the licensee and upon delivery of a faulty component to the licensee. Furthermore, if it is assumed that the design work was performed under contract with the fabrication organization (not the licensee), only the fabricated component that was directly procured by the licensee under contract with the fabricator would meet the definition of a basic component and a defect or failure to comply would exist only upon delivery of a faulty component by the fabricator (direct supplier) to the licensee.

NUREG-0302, Revision 1, provides further clarifications through responses to questions on various aspects of Part 21 implementation. Response to questions related to this position paper are evaluated below.

Questions related to Section 21.2, Scope:

- The response to Question 5 on page 21.2-3 explains the terms "constructing" and "supplying." It states the term "constructing" has been interpreted to include design, manufacture, fabrication, inspection or testing of a facility or activity which is subject to Part 21 and consulting services related to the facility or activity that are important to safety. The term "supplying" has been defined to mean any entity that is contractually responsible for a basic component used or to be used in a facility or activity which is subject to Part 21. Based on the response provided for this question, a contractual relationship establishing

responsibility for a basic component must exist between the purchaser and the supplier. For a facility other than a power reactor, this is limited to the first tier suppliers of basic components as discussed in the response to Question 21 on page 21.2-7 that is described below.

- Question 14 on page 21.2-6 asked if medical physicists who provide consulting services such as calibration of teletherapy machines are subject to Part 21. The response states the medical physicist would be subject to Part 21 if the individual's services are directly procured by the licensee (the hospital) and the hospital should report if it determines the medical physicist provided incorrect calibration charts which resulted in a substantial safety hazard. The response to this question includes an "If" statement that emphasizes that the individual's services would be subject to Part 21 only where the services are directly procured by the licensee. Based on this response, the services would not be subject to Part 21 as it relates to the hospital if they were procured by another entity such as the equipment supplier.

- The response to Question 21 on page 21.2-7 explains that Part 21 applies to a research reactor licensee under 10 Part 50 and to its first tier suppliers of basic components.

Questions related to Section 21.3(a), Basic Component:

- The response to Question 2 on page 21.3(a)-2 makes it clear that only those items which are safety-related are within the scope of Part 21. This response does not imply that all safety-related items are basic components for non-power reactors.

- Question 3 on page 21.3(a)-2 clarifies that when applied to regulated activities other than nuclear power plants, basic component means a component, structure, system, or part thereof that is directly procured by the licensee of the facility or activity subject to Part 21, in which a defect or failure to comply could create a substantial safety hazard. For power reactors, basic component goes down all tiers of the supply or procurement chain to all activities within the chain that have the capability to create a substantial safety hazard.

- Question 5 on page 21.3(a)-3 clarifies that Part 21 applies to suppliers of consumables such as welding materials and calibration services related to a basic component and a deviation from specified requirements of a procurement document, or failure to comply, could create a substantial safety hazard. To apply this clarification to facilities other than power reactors, the consumable or service would have to be related to a basic component and directly procured by the licensee as described in the response to Question 14 on page 21.2-6. Part 21 would not apply for facilities other than power reactors if the consumable or service was related to a component that is not a basic component or if the consumable or service was not directly procured by the licensee.

- The response to Question 11 on page 21.3(a)-4, explains that the meaning of "component hardware" as used in Section 21.3(a) includes all physical elements included in the term basic component (plant, structure, system, component, or part). The response further states that dosimetry services do not constitute design, inspection, testing, or consulting services that are associated with a basic component as defined in section 21.3(a). Based on this response,

design, inspection, testing, or consulting services must be associated with a basic component as defined in section 21.3 to be basic component.

- Question 12 on page 21.3(a)-5 clarifies the statement in 10 CFR 21.3 that "In all cases, "basic component" includes design, inspection, testing, or consulting services "important to safety…" The response to Question 12 explains that activities which could in themselves result in creating or identifying a defect in associated hardware, system, or structure are included in the definition of basic component. The response further states "An organization may accomplish all of these activities in-house or may choose to authorize others to do some of the safety-related activities, e.g., consultation, design, inspection or tests, for it. When such contractual arrangements are made for safety-related services, the organization accomplishing the service is within the scope of Part 21." Based on the response to this question and the understanding that basic components are directly procured for facilities other than power reactors, safety-related services that are performed in-house (not under a contractual arrangement) are not within the scope of Part 21 for facilities other than power reactors.

Questions related to Section 12.3(d), Defect:

- The response to Question 1 on page 21.3(d)-1 discusses that the basic element in determining whether a basic component has been delivered is when the purchaser has taken control over the item. This would typically be at the point the component is received from the supplier. In cases where the purchaser is entitled through contractual provision or ordinary commercial practice, to conduct a receipt inspection before taking final acceptance, delivery would not occur, and notification by the purchaser would not be required where the purchaser conducts the authorized receipt inspection and rejects and returns the component to the supplier within a reasonable period of time after receipt of the component. The supplier of the rejected component would be required to evaluate the deviation and report an identified defect if he had delivered components with similar deviations to other facilities or activities subject to Part 21. As with the responses to other questions discussed above, this response relies upon the existence of a contractual relationship between the purchaser and supplier.

- The response to Question 3 on page 21.3(d)-2 explains that the rule makes no distinction between inter and intra entity delivery of components as long as the transaction occurs pursuant to a procurement document. It further explains that in determining whether a component has been delivered, the basic element is when the purchaser has taken control over the item. Since "delivery" as described in the response to this question requires that the transaction occurs pursuant to a procurement document and that the purchaser has taken control over the item, the response to this question confirms that a contractual relationship between the purchaser and supplier is necessary for the item to be a basic component.

Questions related to Section 21.21(b)(1) of – Notifications of failure to comply or existence of a defect:

- Question 14 on page 21.21(b)(1)-5 asks for an explanation of the difference between various NRC reporting requirements. Within the response to this question on page 21.21(b)(1)-11, there is a discussion of the portion of the Part 21 definition of a basic component that states

"In all cases, 'basic component' includes design, inspection, testing, or consulting services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others." The response explains that "with this very broad definition of basic component, any company providing services or activities which have a safety relationship to a defined basic component are subject to the rule." The response includes reference to a figure for determining reportability specifically for power reactors (the process described in the figure could also be applied to facilities other than power reactors if the applicable basic component definitions were substituted for the power reactor definition) and describes the logic process for determining reportability as:

1. A problem that involves a basic component exists,
2. A potential defect exists,
3. An evaluation determines whether the defect could create a substantial safety hazard.

Based on this discussion, it is clear that the intent of the definition of basic component discussed in the response to this question is to include within the definition of basic component those safety-related services and activities that are associated with "defined" basic components when determining reportability. For non-power reactor facilities, this is limited to the first tier of suppliers and does not extend further down the supply and procurement chain.

Based on the clarifications and changes to the original draft rule described above, it is clear that the plain language reading of the final rule is that "directly procured" means that a structure, system, component, or part thereof, including safety-related services associated with the "defined" basic component hardware, is purchased directly by the licensee from an organization that is contractually responsible for the basic component used or to be used in a facility based on a contract that defines the requirements which the facility or basic component must meet in order to be considered acceptable by the licensee.

Therefore, for facilities other than power reactors, a basic component is a structure, system, component, or part thereof, including safety-related services associated with the basic component hardware, that affects a safety function, is purchased directly by the licensee from an organization that is contractually responsible for the component or service associated with the component based on requirements defined in a contract that must be met for the component or service to be considered acceptable to the licensee, and in which a deviation in a delivered component from the contract requirements or failure to comply could create a substantial safety hazard. This does not include all safety related SSCs utilized at a facility other than a nuclear power reactor within the scope of the definition of basic components in the rule as issued.

3.2 Application of Definition of Basic Components for Hermes Reactors and Reporting Requirements

Basic Component Definition

Kairos Power is implementing a vertical integration business strategy for the Hermes Reactors that includes designing, licensing, and manufacturing most major systems and components for constructing, owning, and operating the Hermes series of test reactors. This strategy is unique and

the number of safety-related components that are expected to be purchased by Kairos Power for installation and use in the Hermes facility is very small.

As discussed above, the definition of basic component for facilities other than power reactors includes three criteria, all of which must be satisfied:

- The component affects a safety function,
- The component is directly procured by Kairos Power for use in a Hermes test reactor facility, and
- In which defect or failure to comply with any applicable regulation, order, or license issued by the Commission in the component could create a substantial safety hazard.

For Hermes test reactors, items that meet all three of the above criteria are basic components. These items include:

1. Structures, systems, components, and parts thereof that are directly procured by Kairos Power from a supplier that is contractually responsible for the safety-related requirements of the component for use in the Hermes Reactor facility in accordance with procurement documents in which a defect or failure could create a substantial safety hazard.
2. Design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with basic component hardware that are directly procured by Kairos Power from suppliers that are contractually responsible for the safety-related requirements in accordance with procurement documents.
3. Materials and supplies that are directly procured by Kairos Power as basic components under a supplier's 10 CFR 50, Appendix B, quality program in accordance with procurement documents.

Items that do not meet all three of the above criteria are not basic components in accordance with the rules. These items include:

1. Non-safety related structures, systems, components, and parts thereof. (NUREG-0302, Question 2 on page 21.3(a)-1)
2. Safety-related structures, systems, components, and parts thereof that are manufactured by Kairos Power. These items are not delivered pursuant to procurement documents that describe the contractual acceptance requirements to a supplier (NUREG-0302, Question 12 on page 21.3(a)-5 and Question 3 on page 21.3(d)-2). Safety-related structures, systems, components, and parts thereof manufactured by Kairos Power are subject to the Hermes Quality Assurance Program requirements, including the requirements for corrective action. The Corrective Action Program requires Significant Conditions Adverse to Quality be identified and actions be taken to correct the identified conditions.
3. Safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services performed by Kairos Power. These items are not delivered pursuant to procurement documents that describes the contractual acceptance requirements to a supplier (NUREG-0302, Question 12 on page 21.3(a)-5 and Question 3 on page 21.3(d)-2). Safety-related activities performed by Kairos Power are subject to the Hermes Quality Assurance Program requirements, including requirements for corrective action. The Corrective Action

Program requires Significant Conditions Adverse to Quality be identified and actions be taken to correct the identified conditions.

4. Safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services procured by Kairos Power that are not associated with basic component hardware. (NUREG-0302, Question 5 on page 21.3(a)-3 and Question 14 on page 21.21(b)(1)-11)
5. Materials and supplies not directly procured by Kairos Power for use "as purchased," but are to be used in the manufacturing, fabrication, and construction of safety-related structures, systems, components, and parts thereof, that are not basic components and that are not procured under a 10 CFR 50, Appendix B, quality program (NUREG-0302, Question 5 on page 21.3(a)-3 and Question 14 on page 21.21(b)(1)-11). Kairos Power is responsible for ensuring that the design requirements of the safety-related structures, systems, components, and parts thereof that are manufactured in-house are satisfied in accordance with the Hermes Quality Assurance Program. This includes the responsibility for verifying the requirements of materials and supplies that are not procured as basic components to be used in the manufacture of safety-related components.
6. Materials and supplies purchased from a sub-supplier by a direct supplier of a basic component to Kairos Power for use in a Hermes Reactor basic component because these materials are not supplied by a first-tier supplier to Kairos Power (NUREG-0302, Question 21 on page 21.2-7 and Question 3 on page 21.3(a)-2). The direct supplier of the basic component is responsible for verifying the design requirements of the materials and supplies that are procured from sub-suppliers for use in the manufacture of the basic component are satisfied.

To illustrate the application of the basic component definition to a safety-related component for the Hermes reactor facility, the following simplified hypothetical examples are provided. These examples may not include all process steps and activities associated with designing and manufacturing components for the Hermes facility. The Hermes Quality Assurance Plan requirements apply to all safety-related activities for the Hermes facility, unless another quality program is specified in a procurement document. The classification of an SSC, or part thereof, as a basic component does not impact the application of the Hermes Quality Assurance Plan requirements.

Example 1: The Decay Heat Removal System (DHRS) is a safety-related system that is designed by Kairos Power personnel. The DHRS design is then used by Kairos Power to fabricate and manufacture various system components, including thimble tube banks, that will be used in the construction of the DHRS for the Hermes facility. DHRS design, manufacturing, and construction activities are performed by Kairos Power under the Hermes Quality Assurance Plan. These activities are not performed pursuant to procurement documents.

- In this example, the DHRS design work is not a basic component because it is not directly procured from a supplier under a contract between the licensee and the designer in

accordance with a procurement document (NUREG 0302, Question 12 on page 21.3(a)-5 and Question 3 on page 21.3(d)-2).
    - Note: If the DHRS thimble tube bank design was performed by a supplier and subsequently manufactured by Kairos Power, it would not be a basic component because the design work is not associated with a "defined" basic component (the hardware is fabricated/manufactured by Kairos Power). (NUREG-0302, Question 5 on page 21.3(a)-3 and Question 14 on page 21.21(b)(1)-11)
- In this example, Kairos Power purchases bulk piping and other materials for use in the manufacturing of DHRS thimble tube banks. These "raw" materials are not basic components because they are not directly procured by Kairos Power for use "as purchased" in a basic component of the Hermes facility. That is, before these materials can be used in the Hermes facility, Kairos Power must perform manufacturing processes such as fabrication, welding, inspections, testing, and other mechanical processing to transform these raw materials into a form that can be used in the Hermes facility and the Kairos Power manufactured component is not a basic component (NUREG-0302, Question 5 on page 21.3(a)-3 and Question 14 on page 21.21(b)(1)-11).
- In this example, Kairos Power subsequently manufactures the DHRS thimble tube banks using the raw materials purchased for the task. As with the design work, the manufacturing work is not performed under a contract between the licensee and the manufacturer in accordance with a procurement document (because in this case, they are the same entity). Therefore, the thimble tubes manufactured by Kairos Power are not basic components (NUREG 0302, Question 12 on page 21.3(a)-5 and Question 3 on page 21.3(d)-2). During manufacturing, Kairos Power would be responsible for ensuring the design requirements of the safety-related components, including verifying the requirements of raw materials and supplies used in manufacturing, are satisfied in accordance with the Hermes Quality Assurance Program.
- Any subsequent non-destructive testing of the fabricated thimble tubes is performed in accordance with applicable code requirements and design specifications. This testing is also not a basic component because it is not associated with basic component hardware (the thimble tubes are not basic components), even if the testing were procured from an outside supplier (NUREG-0302, Question 5 on page 21.3(a)-3 and Question 14 on page 21.21(b)(1)-11).

Example 2: The DHRS is a safety-related system that is designed by Kairos Power personnel under the Hermes quality program. To fabricate/manufacture the thimble tube banks, Kairos Power enters into a contract to directly procure the thimble tube banks from a supplier based on the DHRS design and performance specification provided by Kairos Power.

- In this example, the thimble tube bank supplier manufactures the DHRS thimble tube banks in accordance with the approved design as specified in the procurement document for use as supplied in the Hermes facility. The thimble tube banks are basic components because they are directly procured by Kairos Power for use as procured in the Hermes facility. (NUREG 0302, Question 12 on page 21.3(a)-5 and Question 3 on page 21.3(d)-2)

    - Alternatively, the tube bank supplier manufactures the banks in accordance with the design specification, but Kairos Power retains the responsibility for ensuring the tube bank can adequately perform its intended function. In this case, the tube bank is not a basic component because it is not directly procured for use as supplied from a contractually responsible supplier. Before the tube bank can be used, further special inspection and/or testing must be performed by Kairos Power to ensure it can perform its intended function and the results documented to represent a difference from the as-supplied tube bank. (NUREG-0302, Question 5 on page 21.2-3)
  - In this example, although the tube bank is a basic component, the DHRS design work is not a basic component because it is not directly procured from a supplier under a contract between the licensee and the designer in accordance with a procurement document. (NUREG 0302, Question 12 on page 21.3(a)-5 and Question 3 on page 21.3(d)-2)
    - Alternatively, if the DHRS thimble tube bank was also designed by the fabrication supplier under the contract with Kairos Power, it would be a basic component because it is associated with basic component hardware and is directly procured by Kairos Power from the first-tier supplier. (NUREG 0302, Question 5 on page 21.2-3 and Question 12 on page 21.3(a)-5)
    - Alternatively, if the DHRS thimble tube bank design was performed by another supplier under a separate contract with Kairos Power, it would be a basic component because it is associated with basic component hardware and is directly procured by Kairos Power. (NUREG 0302, Question 14 on page 21.2-6)
    - Alternatively, if the DHRS thimble tube bank design was performed by another sub-supplier under a contract with the supplier of the thimble tube banks, it would not be a basic component because it is not directly procured by Kairos Power (NUREG 0302, Question 14 on page 21.2-6).
- In this example, the thimble tube bank supplier purchases bulk piping and other raw materials for use in the manufacturing of DHRS thimble tubes. These materials are not basic components because they are not directly procured by Kairos Power (NUREG 0302, Question 12 on page 21.3(a)-5 and Question 3 on page 21.3(d)-2).
- Non-destructive testing of the thimble tube banks performed by the thimble tube bank supplier in accordance with code requirements as specified in the procurement document is a basic component because it is associated with basic component hardware and is directly procured by Kairos Power from the first-tier supplier (NUREG 0302, Question 5 on page 21.2-3 and Question 12 on page 21.3(a)-5).
    - Alternatively, if the testing is performed by a sub-supplier under a contract with the thimble tube bank supplier, it would not be a basic component because it is not directly procured by Kairos Power (NUREG 0302, Question 14 on page 21.2-6).

Reporting Requirements

With the above understanding of the definition of "basic component," the reporting requirements for the Hermes facility in accordance with 10 CFR 21.21 and 10 CFR 50.55(e) can be determined.

- Both 10 CFR 21.21(d)(1)(i) and 10 CFR 50.55(e)(4)(i) require notification when information is obtained reasonably indicating a failure to comply for a facility that is related to a substantial safety hazard. These notification requirements do not rely on the definition of "basic component," "defect," or "deviation." Reporting is required if information reasonably indicates that a failure to comply exists within a portion of the Hermes facility relating to a substantial safety hazard.

  An example scenario that could require notification under these requirements would be the discovery that a requirement of a construction code specified in the NRC issued facility license for a safety-related component manufactured by Kairos Power was not met in an item that has been designated for use. This condition could call into question the ability of the item to perform its safety-related function. The failure to meet the code requirement could be related to design, materials, manufacturing, and/or testing activities. If an evaluation of the discovered condition determines that the failure to comply with the code requirement is related to a substantial safety hazard, Kairos Power would be responsible for reporting the discovery in accordance with 10 CFR 21.21(d)(1)(i) and/or 10 CFR 50.55(e)(4)(i).

The remaining reporting requirements rely on the definitions of "basic component," "defect," "deviation," and "procurement document" to determine their applicability. Application of these definitions to facilities other than nuclear power plants is described below:

For 10 CFR Part 21 and 10 CFR 50.55(e), the definitions of "defect," "deviation," and "procurement document" are similar. These definitions with differences noted as they apply to facilities other than nuclear power plants are:

- A defect is defined as:
  - a deviation in a basic component delivered to a purchaser for use in a facility if, on the basis of an evaluation, the deviation could create a substantial safety hazard, and
  - the installation, use, or operation of a basic component containing a defect, and
  - a deviation in a portion of a facility subject to the construction permit requirements of Part 50, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard (for Part 21 only, and the portion of the facility containing the deviation has been offered to the purchaser for acceptance), and
  - for Part 21 only, a condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit as defined in the technical specifications of a license for operation issued under Part 50.
- A deviation is defined as a departure from the technical requirements (or for 10 CFR 50.55(e) only, quality assurance requirements) included in
  - a procurement document,
  - for 10 CFR 50.55(e) only, safety analysis report, construction permit, or other documents provided for basic components installed in a facility subject to the regulations of this part.
- A procurement document is defined as a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Changes to 10 CFR Part 21 and 10 CFR 50.55(e) were published in Federal Register notice 56 FR 36091 (July 31, 1991). The purpose of these changes was to eliminate duplicative reporting of defects, clarify the criteria for reporting defects, and establish uniform time periods for reporting and uniform requirements for the content of reports of defects. These changes expanded the scope of 10 CFR 50.55(e) to include Construction Permit holders for facilities other than nuclear power plants. The background information included in this notice explained that Part 21 was intended to implement section 206 of the Energy Reorganization Act of 1974 which requires reporting of the discovery of "defects" in "basic components" that could create a "substantial safety hazard." It also pointed out a slight difference in the definition of deviation in Part 21 and the proposed 10 CFR 50.55(e). The basis for this difference is that in applying 10 CFR 50.55(e), basic components will have requirements imposed on them not only by their procurement documents, but other license documents.

As discussed previously, basic components for facilities other than nuclear power reactors must meet three criteria:

- The component affects a safety function,
- The component is directly procured by the licensee of a facility, and
- In which a defect or failure to comply could create a substantial safety hazard.

Based on the understanding of the definitions of these terms described above, application of the remaining reporting requirements for Hermes are evaluated:

- 10 CFR 21.21(d)(1)(i) requires notification when information reasonably indicating a defect affecting the manufacture, construction, or operation of a licensed facility is obtained.

  A defect requires a departure from the technical requirements included in a procurement document that could create a substantial safety hazard to be identified. It also requires the portion of the facility affected by the departure to be accepted by the licensee. This notification requirement does not apply to items that are not purchased from a supplier pursuant to acceptance requirements specified in a procurement document.

  Notification under 10 CFR 21.21(d)(1)(i) could be required if an item, that was purchased directly by Kairos Power from a supplier as a basic component, does not meet the contract-defined Kairos Power acceptance requirements after that portion of the facility in which it is installed is accepted for use. For the deviation to be a reportable defect, an evaluation must determine that it could create a substantial safety hazard. Notification under this requirement would not apply to activities performed by Kairos Power for the Hermes facility since these SSCs are not purchased under a procurement document.

  Using Example 2 discussed in Section 3.2.1, an example scenario that could result in a required notification under this paragraph would be the discovery of an error in the manufacture of the DHRS tube banks by the responsible supplier after the DHRS portion of the Hermes facility is designated for use. If an evaluation of the discovered condition

determines that the defect could create a substantial safety hazard, Kairos Power and the supplier would be responsible for reporting the discovery in accordance with 10 CFR 21.21(d)(1)(i).

Using Example 1 discussed in Section 3.2.1, an example scenario that would not result in a required notification under this paragraph would be the discovery of an error that occurred during the manufacturing of the DHRS tube banks by Kairos Power because there is no procurement document associated with the DHRS tube banks. While this condition would not be a defect, the error could result in a failure to comply that would need to be evaluated to determine if it could create a substantial safety hazard that would be reportable.

- 10 CFR 21.21(d)(1)(ii) requires notification when information reasonably indicating a failure to comply or a defect affecting a basic component that is supplied for a facility is obtained.

  As discussed previously, a basic component is directly procured by a licensee from a supplier in accordance with contractual requirements specified in a procurement document. For the Hermes facility, notification under 10 CFR 21.21(d)(1)(ii) would be required for failures to comply and defects identified in safety related SSCs that are directly procured as a basic component and accepted by Kairos Power. This requirement would not apply to SSCs manufactured by Kairos Power for use in the Hermes facility since these SSCs are not basic components.

  To illustrate these requirements for notifications in practice, consider an example based on Example 2 from Section 3.2.1 of this paper. In this example, Kairos Power discovers an error in the thimble tube banks after it has accepted the components. The discovered error had occurred during the manufacturing of the DHRS tube banks by the supplier and resulted in the acceptance requirements for the tube banks (as defined in the procurement document) not being met. If an evaluation of the discovered condition determines that the defect and/or failure to comply is related to a substantial safety hazard, Kairos Power and the supplier would be responsible for reporting the discovery in accordance with 10 CFR 21.21(d)(1)(ii).

- 10 CFR 50.55(e)(4)(ii) requires notification when information reasonably indicating any defect in the construction or manufacture, or any defect found in the final design of a facility as approved and released for construction or manufacture is obtained.

  A defect, as defined in 10 CFR 50.2, requires a departure from technical and quality assurance requirements provided for basic components installed in a facility. These technical and quality assurance requirements must be defined in procurement documents, safety analysis report, construction permit, and other documents provided for basic components. For the Hermes facility, notification under 10 CFR 50.55(e)(4)(ii) would be required for defects identified in safety related SSCs that are directly procured by Kairos Power from a supplier as basic components. Notification under this requirement would not apply to SSCs manufactured by Kairos Power for use in the Hermes facility since these SSCs are not purchased under contract and are not basic components.

4 REGULATORY POSITION

After review of the applicable NRC regulations, it is concluded that the population of SSCs that are basic components in accordance with 10 CFR Part 21 and 10 CFR 50.55(e) for Hermes non-power reactors will include:

1. Structures, systems, components, and parts thereof that are directly procured by Kairos Power from a supplier that is contractually responsible for the safety-related requirements of the component for use in the Hermes reactor facility in accordance with procurement documents in which a defect or failure could create a substantial safety hazard.
2. Design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with basic component hardware that are directly procured by Kairos Power from suppliers that are contractually responsible for the safety-related requirements in accordance with procurement documents.
3. Materials and supplies that are directly procured by Kairos Power under a supplier's 10 CFR 50, Appendix B, quality program.

SSCs that are not basic components in accordance with 10 CFR Part 21 and 10 CFR 50.55(e) for Hermes non-power reactors include:

1. Non-safety related structures, systems, components, and parts thereof.
2. Safety-related structures, systems, components, and parts thereof that are manufactured by Kairos Power.
3. Safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services performed by Kairos Power.
4. Safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services directly procured by Kairos Power that are not associated with an item that is a basic component.
5. Materials and supplies purchased by Kairos Power for use in the Kairos Power-performed manufacturing, fabrication, and construction of safety-related structures, systems, components, and parts thereof, that are not basic components.

Notifications in accordance with 10 CFR 21.21(d)(1) and 10 CFR 50.55(e)(4) are required for the Hermes facility when information that reasonably indicates that any of the following conditions exist:

1. A failure of the Hermes facility to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission that is related to a substantial safety hazard.
2. The manufacture, construction, or operation of the Hermes facility is affected by safety-related items purchased by Kairos Power directly from a supplier as basic components that do not meet the contract-defined Kairos Power acceptance requirements.
3. Failures to comply or defects identified in safety related SSCs that are directly procured by Kairos Power from a supplier as basic components and in which a defect or failure to comply could create a substantial safety hazard.

5 REFERENCES

1. NUREG 0302, Revision 1, “Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) For Reporting of Defects and Noncompliances,” July 1977.