UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

KAIROS POWER LLC – FINAL U.S. NUCLEAR REGULATORY COMMISSION TECHNICAL ASSESSMENT REGARDING WHITE PAPER: "BASIC COMPONENT DEFINITION FOR KAIROS POWER NON-POWER TEST REACTORS" (EPID L-2024-LRO-0013)

SPONSOR INFORMATION

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DOCUMENT INFORMATION

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Purpose of the White Paper: In summary, Kairos Power LLC (Kairos) stated that the purpose of the white paper is to confirm their understanding of the definitions of the term "basic component" as it applies to the Hermes non-power test reactors considering their "vertically-integrated strategy of performing most safety-related design and manufacturing work internally." Kairos is seeking this clarification in order to support their understanding of compliance with the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21, "Notification of failure to comply or existence of a defect and its evaluation," and 10 CFR 50.55(e)(4), "Notification."

Action Requested: Kairos Power requests that the Nuclear Regulatory Commission (NRC) staff review the white paper entitled "Basic Component Definition for the Hermes Non-Power Test Reactors," and provide written confirmation or other feedback on Kairos's understanding of the definitions of the term "basic component" as it applies to the Hermes facilities to support compliance with 10 CFR Part 21 and 10 CFR 50.55(e).

Background

The NRC staff provided draft feedback and observations to Kairos (ML24214A165) to support a discussion during a public meeting on August 30, 2024 (ML24250A120). The NRC staff has completed its review of Kairos's white paper and provides the assessment below. The assessment focuses on the safety issue associated with situations when a defect in a basic component could represent a potential substantial safety hazard and describes how the Part 21

notifications can be implemented without inhibiting Kairos's innovative approach to manufacturing. Enclosure 1 further describes the NRC staff's position illustrated with examples from Kairos's white paper. Enclosure 2 contains detailed information regarding the NRC staff's regulatory interpretation of the regulations and applicable guidance.

This assessment does not contain any regulatory findings on any specific licensing matter. This assessment is also not intended to be comprehensive. Lack of NRC comment regarding a certain aspect of the white paper should not be interpreted as the NRC staff's agreement with Kairos's position. The Office of the General Counsel has reviewed this assessment and both enclosures and has no legal objection.

Overview

The regulations in 10 CFR Part 21 (Part 21) were finalized in 1977 to implement Section 206 of the Energy Reorganization Act (ERA) of 1974, as amended. Part 21 requires, in part, "…organizations building, operating or owning NRC-licensed facilities or conducting NRC-licensed activities, to report failures to comply with regulatory requirements and defects in components which may result in a substantial safety hazard." (42 FR 28892) In its white paper, Kairos acknowledges that 10 CFR Part 21 is applicable to the Hermes facilities and that Kairos is required to report all failures to comply with Part 21. Kairos's position is also that components that Kairos manufactures are not considered "basic components" based on their interpretation of the definition of basic components for a facility other than a power reactor and, therefore, Kairos is not required to report defects for components manufactured by Kairos. The NRC staff reviewed the white paper and disagrees with Kairos's interpretation of the definition of "basic component" for the reasons summarized below.

Safety Importance of the Part 21 Reporting Requirements

Defect reporting requirements provide the NRC with awareness of issues that could create substantial safety hazards in NRC-licensed facilities. Reporting defects starts the process of NRC evaluation of the impact of the defect on safety for specific licensed facilities, as well as potentially broader implications for other regulated facilities and activities. This process supports the NRC's ability to effectuate the purposes of the Atomic Energy Act and Energy Reorganization Act, assuring safety by making the NRC aware of defects that could create substantial safety hazards, and obviating the need for informing other potential licensing or oversight actions by the NRC, such as inspections, requests for information, generic communications, or guidance development.

Since the Hermes test reactor facilities demonstrate a first-of-a-kind technology, they will provide critical experience and lessons learned for Kairos, the NRC, and the broader regulated nuclear industry. The potential issues that could arise in the basic components developed by Kairos could be applicable to more than just the Hermes facilities and there could be significant unknowns given the first-of-a-kind nature of the technology. Therefore, it is important that defects associated with the Hermes facilities are reported and understood to prevent a situation that could create a substantial safety hazard for any NRC-regulated facility.

Implementation of 10 CFR Part 21 Reporting Requirements

During the August 30, 2024, public meeting (ML24250A120), Kairos discussed potential challenges with implementing 10 CFR Part 21 under their vertically integrated structure. The NRC believes the current guidance associated with 10 CFR Part 21 already addresses Kairos's vertically integrated structure and that, for the purposes of 10 CFR Part 21 and 10 CFR 50.55(e) reporting, there can be a clear delineation between Kairos's manufacturing activities and the receipt of a basic component manufactured by Kairos for the Hermes facilities.

The NRC staff's position is that reporting requirements do not extend to issues identified during in-process manufacturing or inhibit Kairos's innovative approach to manufacturing. However, when components are designed, manufactured, tested, and then delivered to the installation organization and contain a defect that could represent a substantial safety hazard, then reports are necessary and important as discussed above. One area for clarification is around the concept of "delivered," which is important because it determines when an identified defect needs to be reported under 10 CFR Part 21 and 10 CFR 50.55(e).

Regulatory Guide (RG) 1.234, Revision 1, "Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21," (ML24038A311) endorses NEI 14-09, Revision 1 (ML16054A825).[1] NEI 14-09, Revision 1, includes the following discussion on the concept of "delivered."

> *The concept of "delivered" is not addressed specifically when the basic component is turned over from one corporation or separate entity to another corporation or entity or delivered within a single corporation. The rule makes no distinction between inter and intra organization delivery of components as long as the transaction occurs pursuant to a procurement document**. In determining whether a basic component has been delivered, the fundamental element is when the purchaser has taken control over the item. For example, if the fabricator of the component is also the licensee of the reactor, the point of delivery is when the organization authorized to use it as a basic component has taken control over the item*** [emphasis added].

Therefore, based on this discussion, the NRC staff's position is that for basic components manufactured by the licensee, Kairos should establish the point of delivery consistent with the point of delivery for components received from an external supplier. In all cases, the point of delivery for SSCs "is when the organization authorized to use it as a basic component has taken control over the item." This is consistent with the NRC-endorsed NEI 14-09, Revision 1, and ensures that defects in basic components are identified and reported consistent with the regulatory requirements under 10 CFR Part 21 and the statutory requirements under Section 206 of the ERA.

Ultimately, implementing 10 CFR Part 21 and 10 CFR 50.55(e) for facilities other than power reactors in which the licensee manufactures safety-related components should not be

[1] The NRC acknowledges that NEI 14-09 and RG 1.234, as a whole, are applicable to power reactors but the concept of "delivered" is applicable to non-power reactor facilities such as Hermes and Hermes 2 through the definition of defect in 10 CFR 21.3, which states that a defect is a deviation in a basic component that has been "delivered." 10 CFR Part 21 reporting requirements apply only to deviations in basic components that have been "delivered."

substantially different than for a licensee that uses external suppliers for all of its safety-related components.

Enclosure 1 contains additional information regarding the NRC position illustrated with examples from the white paper.

Summary of NRC Staff Position

In its white paper, Kairos states its position that the 10 CFR Part 21 and 10 CFR 50.55(e) reporting requirements are limited only to structures, systems, and components (SSCs) that are provided to Kairos by another organization under contract and do not encompass components designed and manufactured by Kairos. Kairos believes that its position is consistent with the scope and purpose of the regulations in 10 CFR Part 21, 10 CFR Part 50, Section 206 of the ERA, as well as specific responses and statements in NUREG-0302, Revision 1 and NEI 14-09, Revision 1.

The NRC staff disagrees that Kairos's position is consistent with the applicable law and regulations. The scope of basic components for the Hermes facilities would include components manufactured by Kairos as well as those provided to Kairos by another organization under contract. The 10 CFR Part 21 and 10 CFR 50.55(e) reporting requirements provide the NRC with awareness of issues that could create substantial safety hazards at the Hermes test reactor and other NRC-licensed facilities. Current NRC-endorsed guidance already addresses Kairos's "unique" strategy. For basic components manufactured by Kairos, the point of delivery should be established "when the organization authorized to use it as a basic component has taken control over the item." After delivery, identified failures to comply and defects must be evaluated to determine if they represent a potential substantial safety hazard and, if so, reported under 10 CFR Part 21 and 10 CFR 50.55(e).

Enclosure 2 contains additional information regarding the NRC staff's regulatory interpretation of the regulations and applicable guidance.

REFERENCES

1. U.S. Nuclear Regulatory Commission, *Title 10 of the Code of Federal Regulations*, (10 CFR) Part 21, “Reporting of Defects and Noncompliance.”
2. U.S. Nuclear Regulatory Commission, *Title 10 of the Code of Federal Regulations*, (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities.”
3. Energy Reorganization Act of 1974, Section 206, “NONCOMPLIANCE,” as amended through P.L. 109-58, Enacted, dated August 8, 2005.
4. U.S. Nuclear Regulatory Commission, 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,” dated October 1977, (ML062080399).
5. Regulatory Guide 2.5, Revision 1, “Quality Assurance Program Requirements for Research and Test Reactors,” dated June 2010, (ML093520099)
6. American Nuclear Society/American National Standards Institute (ANS/ANSI) 15.8, “Quality Assurance Program Requirements for Research Reactors,” dated September 12, 1995.
7. American Nuclear Society/American National Standards Institute (ANS/ANSI) 15.1, “The Development of Technical Specifications for Research Reactors,” dated April 20, 2007.
8. Regulatory Guide 1.234, Revision 1, “Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21,” dated March 2024, (ML24038A311).
9. Nuclear Energy Institute 14-09, Revision 1, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance,” dated February 2016, (ML16054A825).

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Enclosure 1: Discussion of Example Scenarios

In section 3.2, "Application of Definition of Basic Components for Hermes Reactors and Reporting Requirements," of the white paper, Kairos provides examples to illustrate how they apply their understanding of the definition of a basic component. Example 2 starts with a discussion of a scenario where Kairos enters into a contract to directly procure safety-related components from a supplier based on design and performance specifications provided by Kairos. Kairos considers SSCs acquired through this type of scenario to be basic components for which 10 CFR Part 21 and 10 CFR 50.55(e) reporting requirements for defects would apply. The NRC staff agrees with this statement and takes the position that in this example, 10 CFR Part 21 reporting requirements would also be applicable to the supplier.

In the discussion of the alternate scenarios described by Kairos in its white paper, Kairos parses the definition of a basic component into pieces (design, manufacture, testing). These scenarios can be grouped and summarized as follows:

1. Design Performed by Supplier
    - *Description:* The supplier manufactures the component and performs the design work under contract with Kairos.
    - *Kairos's Assessment*: Both the component and design work are considered a basic component because it is directly procured by Kairos.
2. Kairos Retains quality assurance (QA) of Manufacturing
    - *Description:* The supplier manufactures the component under contract with Kairos, but Kairos retains the responsibility for ensuring the components can adequately perform their intended function (e.g., satisfy QA requirements through an approach similar to commercial-grade dedication).
    - *Kairos's Assessment:* The component is not considered a basic component because it is "not directly procured for use as supplied."
3. Sub-contractors
    - *Description:* The supplier is contracted to perform the design, manufacture, and testing (e.g., non-destructive evaluation) of the component. The supplier sub-contracts the design and testing to another supplier. The supplier also procures piping or other raw materials from a sub-supplier.
    - *Kairos's Assessment:* The raw materials, design, and testing work would not be considered a basic component because it was not directly procured by Kairos.

The NRC staff does not see a relevant distinction among these scenarios, because the safety basis for reporting defects under 10 CFR Part 21 is independent of which entity introduced the defect. In all scenarios above, Kairos is responsible for ensuring 10 CFR Part 21 reporting is considered.[2] However, the point at which "delivery" of these components occurs impacts whether reporting requirements apply. The point of delivery should be established consistent with NRC endorsed guidance in NEI 14-09, Revision 1, and occurs when the organization authorized to use it as a basic component has taken control over the item. If during the design, manufacture, or testing of the component a defect is identified, reporting requirements would not apply because the component had not been delivered for installation. Alternatively, if the component has been released to the part of the organization responsible for installation, reporting requirements would apply because it would have been delivered for installation and

[2] NRC staff analysis of scenarios is only considering reporting requirements for Kairos. In groups 1 and 3, reporting requirements are also applicable to suppliers. However, for non-power reactors, sub-contractors would not be responsible under 10 CFR Part 21 to submit reports to the NRC.

use. This approach meets the definition of defect in 10 CFR 21.3, which states that a defect is a deviation in a basic component that has been “delivered.” 10 CFR Part 21 reporting requirements apply only to deviations in basic components that have been “delivered.” The point of delivery is critical to when a potential substantial safety hazard could occur and ensures consistent application of 10 CFR Part 21 to Kairos’s vertically integrated structure.

Enclosure 2: Regulatory Interpretation

Statutory and 10 CFR Part 21 Requirements

Section 206, Noncompliance, of the Energy Reorganization Act of 1974 (P.L. 93–438) states, in part:

> *(a) Any individual director, or responsible officer of a firm* ***constructing, owning, operating, or supplying the components*** [emphasis added] *of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954 as amended, or pursuant to this Act, who obtains information reasonably indicating that such* ***facility or activity or basic components*** [emphasis added] *supplied to such facility or activity–*
>
> > *(1) fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards, or*
> >
> > *(2) contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate, shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.*
>
> *(b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended*.

10 CFR 21.1, "Purpose," states the following:

> *The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm* ***constructing, owning, operating or supplying the components*** [emphasis added] *of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the* ***facility, activity, or basic component*** [emphasis added] *supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.*

10 CFR 21.2(a)(1) states that these regulations apply to "[e]ach individual, partnership, corporation, or other entity applying for or holding a license or permit under the regulations in this chapter […] to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility […]; and each director and responsible officer of such a licensee."

10 CFR 21.2(b) goes on to state that "[f]or persons licensed to construct a facility under […] a construction permit issued under § 50.23 of this chapter […] evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974."

10 CFR 50.55(e)(1) states that "for the purposes of this paragraph, the definitions in § 21.3 of this chapter apply." The notification requirements of 10 CFR 50.55(e)(4), in part, are listed below:

> *(i) The holder of a facility construction permit subject to this part […] 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.*
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> *(ii) The holder of a facility construction permit subject to this part […] 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.*
>
> *(iv) A dedicating entity is responsible for identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items . . . .*

In the preamble to the final 10 CFR Part 21 rule as published in Federal Register (FR) on June 6, 1977 (42 FR 28893), the NRC states the following:

> *"In order that the implementation of Section 206 may be responsive to anticipation of problems before the event,* ***a broad interpretation of "firm constructing, owning, operating or supplying the components" has been used. This interpretation includes not only licensees and organizations that physically construct facilities and physically supply components but also includes organizations that only supply safety-related services such as design, inspection, testing or consultation; e.g., site geological investigations****.*[emphasis added] *This interpretation is intended to bring within the regulations in this part those various organizations that can create a substantial safety hazard considering the various methods available for consultation, procurement, design, construction, testing, inspection and operation. These methods include not only the option where design and construction are accomplished by one organization but also the option where one organization does safety-related consultation, another safety-related design and another the actual construction. Each of these organizations has the capability to generate a defect and a potential for failing to comply."*

Based on these requirements and the discussion in the preamble to the 10 CFR Part 21 rule in 42 FR 28893, the reporting requirements of 10 CFR 21.21 and 10 CFR 50.55(e) apply to all entities responsible for **constructing, owning, operating or supplying components** to a facility licensed under 10 CFR Part 50, including Kairos as the constructor, owner, operator, and supplier of components for the Hermes facilities. The NRC staff also recommends that the interpretation discussed in the preamble to the 10 CFR Part 21 rule should be kept in mind when interpreting the meaning of individual terms within the broader purpose, scope, and definitions of 10 CFR Part 21.

Definition of "Basic Component"

10 CFR 21.3 states, in part, under the definition of "basic component":

> *(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*** [emphasis added] *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.*
>
> *(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.*

Based on part (3) of the "basic component" definition in 10 CFR 21.3, the Kairos Power white paper defines basic components for Hermes as structures, systems, components (SSCs) or parts thereof that meet the following criteria:

a. affects a safety function,
b. are directly procured by the licensee of a facility, and
c. in which a defect or failure to comply could create a substantial safety hazard.

Section 3.1 of Kairos's white paper discusses criterion (b) on the term "directly procured" as follows:

> *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.*

The NRC agrees that basic components must meet criteria (a) and (c) above, consistent with the definition in 10 CFR 21.3. However, Kairos's interpretation of criterion (b) does not appear to fully consider the statutory language in Section 206 of the Energy Reorganization Act (ERA) of 1974, the purpose and scope of the 10 CFR Part 21 rule, and relevant guidance in NUREG-0302, "Remarks Presented (Questions/Answers Discussed) At Public Regional Meetings to Discuss Regulations (10 CFR Part 21) For Reporting Of Defects and Noncompliance," Revision 1, and the Nuclear Energy Institute (NEI) 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1. Given Kairos's "unique" strategy to 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," Kairos's proposed implementation of criterion (b) is too narrowly focused to include only items that are provided to Kairos by another organization under contract. The scope of basic components for the Hermes facilities also includes components manufactured by Kairos that also meet criteria (a) and (c) above as explained in more detail below.

Discussion of "Directly Procured"

In the preamble to the final 10 CFR Part 21 rule (42 FR 28893), the NRC states the following:

> *The organizations subject to the regulations in Part 21 may be many procurement tiers away from the holder of a license to construct or operate a nuclear power reactor. If the license is other than to construct or operate a nuclear power reactor, then the organizations subject to the regulations are those organizations that directly supply the licensee of the facility or activity.*

Kairos notes this portion of the preamble in its white paper, but does not appear to consider this language in their interpretation of the 10 CFR Part 21 regulation. The NRC staff views this language as important to understanding the purpose of the phrase "…that is directly procured by the licensee of a facility or activity subject to the regulations in this part…" from the definition of "basic component" for facilities other than power reactors in 10 CFR 21.3. The preamble clarifies that for power reactors, the Commission considered that the 10 CFR Part 21 reporting requirements may extend "many procurement tiers away" from the licensee, but for facilities other than power reactors the rule was designed to limit these reporting requirements no further than the direct supplier of the licensee. Thus, this portion of the preamble indicates that the intent of the "directly procured" language was to limit how far down the supply chain the 10 CFR Part 21 reporting requirements extend for facilities other than power reactors, not to eliminate components manufactured by the licensee from being identified as basic components.

In contrast to the assertion by Kairos in its white paper, taking into consideration the purpose of the statute and the discussion in the preamble for the final 10 CFR Part 21 rule (42 FR 28893), the "directly procured" language does not remove components manufactured by the licensee from the definition of "basic component." Therefore, the scope of 10 CFR Part 21 reporting requirements for the Hermes test reactor for components manufactured by the licensee includes failures to comply and defects identified by the licensee.

Discussion of “Delivery” and “Procurement Document”

Page 21.3(d)-2 of NUREG-0302, Revision 1, responds to a question regarding the concept of “delivered”:

> *The rule makes no distinction between inter and intra entity delivery of components as long as the transaction occurs pursuant to a procurement document. In determining whether a component has been delivered, the basic element is when the purchaser has taken control over the item.*

In its white paper, Kairos evaluates this response by stating that “[s]ince ‘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.” The NRC observes that Kairos appears to base its evaluation on a narrow interpretation of the definition of a procurement document. But the NRC notes that this response on Page 21.3(d)-2 of NUREG-0302, Revision 1, focuses on when 10 CFR Part 21 should be applied, not whether it should apply. Further, how this response impacts the interpretation of “basic component” depends on the definition of “procurement document.” This response also supports the general interpretation that there is no difference from a 10 CFR Part 21 perspective regarding whether a component is manufactured in-house or from an external organization by stating there is “no distinction between inter and intra entity delivery of components.”

Moreover, the NRC notes that NUREG-0302, Revision 1, (page 5) takes a broad view of the definition of procurement document.

> *The Procurement Document is defined in Part 21 as "A contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser."*
>
> *The definition includes both an inter-organizational and an intraorganizational document that defines the technical requirements. This document is the vehicle by which a supplier is informed that the procurement action comes under Part 21.*

Therefore, because NUREG-0302, Revision 1, states that a procurement document includes an intraorganizational document that defines technical requirements and makes “no distinction between inter and intra entity delivery of components,” the NRC staff interprets “procurement document” to include internal Kairos documents that define the technical requirements of components that could create a substantial safety hazard. Therefore, NUREG-0302, Revision 1, conflicts with Kairos’s narrow interpretation that “procurement document” means something limited to a contractual relationship with an external organization. Accordingly, the NRC staff disagrees with Kairos’s position that the above response on page 21.3(d)-2 of NUREG-0302, Revision 1, confirms that a contractual relationship between the purchaser and supplier is necessary for the item to be a basic component.

Regulatory Guide 1.234, Revision 1 and NEI-14-09, Revision 1

Regulatory Guide (RG) 1.234, Revision 1, "Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21," endorses NEI 14-09, Revision 1.[3] NEI 14-09, Revision 1, includes the following discussion on the concept of "delivered."

> *The concept of "delivered" is not addressed specifically when the basic component is turned over from one corporation or separate entity to another corporation or entity or delivered within a single corporation. The rule makes no distinction between inter and intra organization delivery of components as long as the transaction occurs pursuant to a procurement document**. In determining whether a basic component has been delivered, the fundamental element is when the purchaser has taken control over the item. For example, if the fabricator of the component is also the licensee of the reactor, the point of delivery is when the organization authorized to use it as a basic component has taken control over the item** [emphasis added].*

NEI 14-09, Revision 1, states that if a licensee is also the fabricator of a component, "delivery" occurs when the organization authorized to use the component "has taken control over the item." The NRC staff's position that the definition of "delivery" does not preclude or prevent components fabricated in-house by the licensee from being within the scope of 10 CFR Part 21 is consistent with NEI 14-09, Revision 1. NEI 14-09, Revision 1, also provides clarity on how to define the point of "delivery" in such situations where the component is fabricated in-house by stating "if the fabricator of the component is also the licensee of the reactor, the point of delivery is when the organization authorized to use it as a basic component has taken control over the item."

Regarding part (4) of the 10 CFR Part 21 "basic component" definition, Page 21.3(a)-5 of NUREG-0302, Revision 1, responds to a question clarifying the meaning of basic component:

> ***The broad scope of Section 206 activities of construction, operation, owning and supplying in themselves include activities such as design, consultation or inspection that are important to safety and are associated with component hardware. Thus, such 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. An organization may accomplish all of these activities in-house*** [emphasis added] *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.*

In its white paper, Kairos concludes that "[b]ased on the response to this question [clarifying the meaning of basic component] and the understanding that basic components are directly procured for facilities other than power reactors, safety-related services that are performed in-

[3] The NRC acknowledges that NEI 14-09 and RG 1.234 are applicable to power reactors but the concept of "delivered" is applicable to non-power reactor facilities such as Hermes and Hermes 2 through the definition of defect in 10 CFR 21.3, which states that a defect is a deviation in a basic component that has been "delivered." 10 CFR Part 21 reporting requirements apply only to deviations in basic components that have been "delivered."

house (not under a contractual arrangement) are not within the scope of Part 21 for facilities other than power reactors."

The final sentence of the response on Page 21.3(a)-5 of NUREG-0302, Revision 1, makes clear that the scope of 10 CFR Part 21 extends to organizations providing safety-related services to the licensee but does not create or imply a limitation on the scope of 10 CFR Part 21 that would exclude components manufactured by the licensee. Therefore, the NRC staff disagrees with Kairos's conclusion that safety-related services that are performed in-house are not within the scope of 10 CFR Part 21 and 10 CFR 50.55(e). The response on page 21.3(a)-5 of NUREG-0302, Revision 1, states that the "broad scope of Section 206 activities" such as "supplying" include activities that are important to safety and therefore these activities are included in the definition of basic component. The response also states that organizations may accomplish safety-related activities in-house or via contracts and when contractual arrangements are made for safety-related services the organization accomplishing the service is within the scope of 10 CFR Part 21. Accordingly, as the owner, constructor, operator, and component supplier of the Hermes non-power reactor facilities, safety-related activities, services, and components manufactured by Kairos in-house would be within the scope of 10 CFR Part 21, consistent with the broad scope of Section 206 of the ERA, the purpose and scope of 10 CFR Part 21, and the statements in NUREG-0302, Revision 1 and NEI 14-09, Revision 1 regarding "delivery" and "procurement document" that explicitly do not distinguish between inter-organization or intra-organization processes as discussed above.

Summary of Definition of "Basic Component"

Based on the discussion above, organizations that choose to accomplish safety-related activities in-house, including component manufacturing, must conduct those activities within the scope of 10 CFR Part 21 and 10 CFR 50.55(e). As such, the reporting requirements of 10 CFR 21.21 and 10 CFR 50.55(e) would apply to Kairos as the owner, constructor, operator, manufacturer, and supplier of components to the Hermes facilities. Therefore, if Kairos obtained information reasonably indicating that the Hermes facilities or an activity or component within those facilities fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or contains a defect which would create a substantial safety hazard, Kairos would be required to notify the Commission, regardless of whether the component was provided to Kairos by another organization under contract or designed and manufactured in-house by Kairos. While the 10 CFR Part 21 and 10 CFR 50.55(e) reporting requirements apply to Kairos, the timing of when these notifications will depend on the point of delivery, which Kairos should establish for the SSCs Kairos manufactures consistent with the point of delivery for components received from an external supplier. In all cases, the point of delivery "is when the organization authorized to use it as a basic component has taken control over the item."