

Enclosure 2
Exemption Request to 10 CFR 55 Medical Requirements
(Non-Proprietary)

Exemption Request to 10 CFR 55 Medical Requirements

1 BACKGROUND

Kairos Power LLC (Kairos Power) requests an exemption from certain requirements of 10 CFR 55. The current regulation requires operator license applications and operator requalification applications to include certification of medical fitness of operators as well as document medical records, report on medical conditions, and complete medical examinations every two years. The requested exemption would exempt non-power KP-FHR facility's (Facility) operator applicants from medical certification and the need for documenting medical records, reporting on medical conditions, and completing medical examinations every two years.

The underlying purpose of this requirement is to standardize how the Commission "determines qualifications" for control room operators, as consistent with the Atomic Energy Act of 1954, as amended (AEA) (Reference 1). In the Nuclear Waste Policy Act of 1982, as amended, Section 306, Congress directed the NRC to further promulgate regulations for training and qualification of operators (Reference 2). In response, the NRC amended Part 55 to clarify the requirements for issuing licenses to operators and to describe the process for submitting operator license applications (Reference 3).

KP-FHR technology has a simple, automated operating interface; and relies on passive safety design features that results in reduced reliance on operators when compared to the current operating LWR fleet. This reduced reliance on operators results in KP-FHRs being characterized as self-reliant mitigation facilities. While NRC staff have considered the concept of self-reliant mitigation facilities as part of their draft 10 CFR 53 rulemaking, Kairos Power defines this concept for KP-FHRs as:

1. KP-FHRs do not rely on operator actions to mitigate the consequences of postulated events to ensure that the dose at the site boundary meets regulatory limits.
2. The KP-FHR plant designed response to postulated events relies on safety features and characteristics that will perform their safety function independent of credible human errors of commission or omission and do not require manual human operation in response to equipment failures.
3. The KP-FHR design relies on functional containment, which includes multiple barriers, to prevent the release of radioactive material at risk for release. The primary functional containment barriers are the coating layers of the TRISO fuel, and the secondary functional containment barrier is the reactor coolant. The inherent design features that support the functional containment approach include a near-atmospheric operating pressure, a robust fuel form with radionuclide retention capabilities in transient conditions, and a primary coolant design with a high boiling point that is operated at near-atmospheric pressures preventing energetic releases. These design features do not rely on operator actions and will perform their safety function independent of credible commission or omission of operator actions.

2 REGULATORY REQUIREMENT

The regulation in 55.8(c)(1) requires NRC collection of NRC Form 396:

(1) In §§ 55.23, 55.25, 55.27, 55.31, NRC Form 396 is approved under control number 3150-0024.

The regulation in 10 CFR 55.21 requires that a physician administer an applicant's medical examination every two years to determine if the applicant meets the medical requirements:

An applicant for a license shall have a medical examination by a physician. A licensee shall have a medical examination by a physician every two years. The physician shall determine that the applicant or licensee meets the requirements of § 55.33(a)(1).

The regulation in 10 CFR 55.23 requires that an authorized representative of the facility licensee complete and sign NRC Form 396 to certify each applicant's medical fitness:

To certify the medical fitness of the applicant, an authorized representative of the facility licensee shall complete and sign NRC Form 396, "Certification of Medical Examination by Facility Licensee," which can be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (301) 415-5877, or by visiting the NRC's Web site at <http://www.nrc.gov> and selecting forms from the index found on the home page.

(a) Form NRC-396 must certify that a physician has conducted the medical examination of the applicant as required in § 55.21.

(b) When the certification requests a conditional license based on medical evidence, the medical evidence must be submitted on NRC Form 396 to the Commission and the Commission then makes a determination in accordance with § 55.33.

The regulation in 10 CFR 55.25 requires that the facility licensee must report on an operator's developed permanent physical or mental conditions to the Commission within 30 days:

If, during the term of the license, the licensee develops a permanent physical or mental condition that causes the licensee to fail to meet the requirements of § 55.21 of this part, the facility licensee shall notify the Commission, within 30 days of learning of the diagnosis, in accordance with § 50.74(c). For conditions for which a conditional license (as described in § 55.33(b) of this part) is requested, the facility licensee shall provide medical certification on Form NRC 396 to the Commission (as described in § 55.23 of this part).

The regulation in 10 CFR 55.27 requires the facility licensee to document and maintain medical qualification records while the individual is licensed to operate:

The facility licensee shall document and maintain the results of medical qualifications data, test results, and each operator's or senior operator's medical history for the current license period and provide the documentation to the Commission upon request. The facility licensee shall retain this documentation while an individual performs the functions of an operator or senior operator.

The regulation in 10 CFR 55.31(a)(6) requires the applicant to provide facility licensee medical certification on NRC Form 396:

(6) Provide certification by the facility licensee of medical condition and general health on Form NRC - 396, to comply with §§ 55.21, 55.23 and 55.33(a)(1).

The regulation in 10 CFR 55.31(c) requires that an applicant may submit further medical report as a supplement to their application:

(c) An applicant whose application has been denied because of a medical condition or general health may submit a further medical report at any time as a supplement to the application.

The regulation in 10 CFR 55.33(a)(1) requires that the Commission's approval of an initial application is dependent on the applicant's medical certification:

(1) Health. The applicant's medical condition and general health will not adversely affect the performance of assigned operator job duties or cause operational errors endangering public health and safety. The Commission will base its finding upon the certification by the facility licensee as detailed in § 55.23.

The regulation in 55.33(b) requires that the Commission include medical conditions if the operator applicant's medical condition does not meet the requirements of 10 CFR 55.33(a)(1):

(b) Conditional license. If an applicant's general medical condition does not meet the minimum standards under § 55.33(a)(1) of this part, the Commission may approve the application and include conditions in the license to accommodate the medical defect. The Commission will consider the recommendations and supporting evidence of the facility licensee and of the examining physician (provided on Form NRC-396) in arriving at its decision.

The regulations in 10 CFR 55.57(a)(6) requires that an applicant for renewal provide medical certification on a new NRC Form 396:

(6) Provide certification by the facility licensee of medical condition and general health on Form NRC-396, to comply with §§ 55.21, 55.23 and 55.27.

The regulations in 10 CFR 55.57 (b)(1) requires that the Commission's approval of a renewal application is dependent on the applicant's medical certification:

(1) The medical condition and the general health of the licensee continue to be such as not to cause operational errors that endanger public health and safety. The Commission will base this finding upon the certification by the facility licensee as described in § 55.23.

3 EXEMPTION SOUGHT

Consistent with 10 CFR 55.11, Kairos Power requests NRC approval of exemptions from the following portions of 10 CFR 55:

- 10 CFR 55.21, specifically the requirement for (1) an applicant to "have a medical examination by a physician," (2). for the examination to take place "every two years," and (3) for the physician to "determine that the applicant or licensee meets the requirements of § 55.33(a)(1)."
- 10 CFR 55.23, specifically the requirement for (1) the authorized representative of the facility licensee to "complete and sign NRC Form 396," (2) for the facility to "certify that a physician has conducted the medical examination," and (3) for the facility to submit "medical evidence" to support a conditional license.
- 10 CFR 55.25, specifically the requirements for the facility to "notify the Commission, within 30 days of learning of" a permanent mental or physical condition.
- 10 CFR 55.27, specifically the requirement for the facility to "document and maintain" medical records.

- 10 CFR 55.31(a)(6), specifically the requirement for the facility to “provide certification” on NRC Form 396.
- 10 CFR 55.31(c), specifically the requirement for the applicant to “submit further medical report” as a supplement to their application.
- 10 CFR 55.57(a)(6), specifically the requirement for the applicant to “provide certification by the facility licensee of medical condition and general health” on NRC Form 396.

As a result of these exemptions:

1. The Facility’s initial applicants and license renewal applications approvals by the Commission are based on the qualifications on NRC Form 398, as described in 10 CFR 55.31(a)(1)-(5) and 10 CFR 55.57(a)(1)-(5). The NRC finding and approval in 10 CFR 55.31(a) would be based solely on 10 CFR 55.33(a)(2), because Kairos Power is requesting an exemption from 10 CFR 55.23.
2. The Facility does not submit NRC Form 396, “Certification of Medical Examination by Facility Licensee,” for initial applications and license renewal applications.
3. The Facility’s applicants and licensed operators are exempt from a biennial (every two year) medical examination.
4. The Facility is exempt from reporting on the development of an operator’s permanent physical or mental condition.
5. The Facility is exempt from documenting and maintaining medical records of the applicants and licensed operators.
6. NRC would need to exempt from requiring collection of NRC Form 396 (10 CFR 55.8(c)(1)), basing operator application findings from medical certifications (10 CFR 55.33(a)(1)), from issuing conditions based on medical certifications (10 CFR 55.33(b)), and basing operator renewals from medical certification (10 CFR 55.57(b)(1)).

4 JUSTIFICATION FOR EXEMPTION

The exemption requirements for operator licenses under 10 CFR 55 regulations are specified in 10 CFR 55.11 and allows the NRC to:

...[G]rant such exemptions from the requirements of the regulations in this part as it determines are [A.] authorized by law and [B.] will not endanger life or property and [C.] are otherwise in the public interest.

A. The requested exemption is authorized by law

The Atomic Energy Act of 1954, as amended, requires the Commission to:

- a. prescribe uniform conditions for licensing individuals as operators of any of the various classes of production and utilization facilities licensed in this Act;*
- b. determine the qualifications of such individuals;*
- c. issue licenses to such individuals in such form as the Commission may prescribe; and*
- d. suspend such licenses for violations of any provision of this Act or any rule or regulation issued thereunder whenever the Commission deems such action desirable.*

Importantly, the AEA neither prescribes nor limits the qualifications of licensed individuals, including obtaining and maintaining a medical certification. Rather, the AEA leaves that choice to the discretion of the Commission to determine the qualifications and prescribe uniform conditions. Therefore, the requested exemptions are authorized by law.

B. The requested exemptions will not endanger life or property

As a self-reliant mitigation facility, a KP-FHR relies on passive safety features that are independent of operator interactions (including acts of commission or omission) to mitigate the consequences of postulated events. With the reduced reliance on operators, medical conditions and general health of the operator would not cause operational errors endangering public health and safety. This provides assurance that the requested exemptions will not endanger life or property.

C. The requested exemptions are in the public interest

Non-power KP-FHRs are a key part in the iterative development and deployment of KP-FHR technology. The commercialization of KP-FHR technology will deliver a clean, affordable, and safe energy solution. Kairos Power has an aggressive commercialization timeline to deploy KP-FHRs. Since the regulations require a medical certification per each operator application, the Facility would need to rely on the availability of the NRC Research and Test Reactor division and its resources to verify the medical certification. In the ADVANCE Act of 2024, Title V “Improving Commission Efficiency,” Congress mandated the Commission to update the mission statement to include:

...that licensing and regulation of the civilian use of radioactive materials and nuclear energy be conducted in a manner that is efficient and does not unnecessarily limit – (1) the civilian use of radioactive materials and deployment of nuclear energy; or (2) the benefits of civilian use of radioactive materials and nuclear energy technology to society (Reference 4).

In response to Congress, the NRC updated their mission statement to “enable” the deployment nuclear technology:

The NRC protects public health and safety and advances the nation’s common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials through efficient and reliable licensing, oversight, and regulation for the benefit of society and the environment (Reference 5).

Recent Executive Orders reiterate NRC’s mandate to carry out its mission statement while also considering the benefits of nuclear innovation (Reference 6). Congress, the NRC, and the Executive Branch recognize the importance of efficiently deploying advanced nuclear solutions. The requested exemptions would exempt Facility operators from NRC mandated and controlled medical requirements, providing relief from the limited NRC resources dedicated to non-power operator licensees. This relief, which is authorized by law, would streamline the issuances of operator licenses to enable the deployment of KP-FHR technology on an aggressive timeline without endangering life or property. Therefore, the requested exemption is in the public interest.

5 ENVIRONMENTAL CONSIDERATIONS

The requested exemptions meet the criteria for a categorical exclusion from environmental consideration. The NRC has previously determined the list of categorical exclusions in 10 CFR 51.22(c). The requested exemptions meet criteria (i)-(vi) in 10 CFR 51.22(c)(25) as further described below.

The requested exemptions involve no significant hazards consideration (10 CFR 51.22(c)(25)(i)) because the exemption involves only a change in the medical qualifications, which is programmatic in nature, and does not introduce any new significant hazards that could impact the environment.

The requested exemptions involve no significant changes in the types or significant increases in the amounts of any effluents that may be released offsite (10 CFR 51.22(c)(25)(ii)) because the exemption involves only a change in the medical qualifications, which is programmatic in nature, and does not involve any changes in the types or increase in the amounts of effluents that may be released offsite.

The requested exemptions involve no significant increases in individual or cumulative public or occupational radiation exposure (10 CFR 51.22(c)(25)(iii)) because the exemption involves only a change in the medical qualifications, which is programmatic in nature, and does not contribute to any significant increase in individual or cumulative public or occupational radiation exposures.

The requested exemptions involve no significant construction impacts (10 CFR 51.22(c)(25)(iv)) because the exemption involves only a change in the medical qualifications, which is programmatic in nature, and does not involve any construction impact.

The requested exemptions involve no significant increase in the potential for or consequences from radiological accidents (10 CFR 51.22(c)(25)(v)) because the exemption involves only a change in the medical qualifications, which is programmatic in nature, and does not impact the potential for consequences from radiological accidents.

Lastly, the requested exemptions involve recordkeeping (10 CFR 51.22(c)(25)(iv)(A), reporting (10 CFR 51.22(c)(25)(vi)(B)), and the education, training, experience, qualification, requalification, or other employment suitability requirements (10 CFR 51.22(c)(25)(vi)(E)) because the exemption sought is specific to the medical qualifications of reactor operators. Therefore, the requested exemption meets the criteria for categorical exclusion.

6 CONCLUSION

On the basis of the information presented, Kairos Power requests that the NRC grant the exemptions from 10 CFR 55 as noted above for non-power KP-FHR facility licenses.

7 REFERENCES

1. Atomic Energy Act of 1954, as amended, "Operators' Licenses," Section 107. April 4, 2024.
2. Nuclear Waste Policy Act of 1982, as amended, "Nuclear Regulatory Commission Training Authorization," Section 306. March 2004.
3. Nuclear Regulatory Commission, "Operator licenses and Conforming Amendments," Federal Register, Vol. 52, No. 57, 52 FR 9460. March 25, 1987.
4. Division B - ADVANCE Act of 2024, Title V, "Improving Commission Efficiency," Section 501.
5. Nuclear Regulatory Commission, "NRC Approves Updated Mission Statement," Office of Public Affairs, No. 25-005. January 24, 2025.
6. Executive Order. "Ordering the Reform of the Nuclear Regulatory Commission, 14300, 2025" Federal Register Vol 90, No. 102 (May 23, 2025): 22587.
<https://www.govinfo.gov/content/pkg/FR-2025-05-29/pdf/2025-09798.pdf>