NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for a hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with the NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contracting the NRC Meta System Help Desk thorough the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll free call to 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an extension request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First-class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party using E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is available to the public at *http://ehd1.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 20th day of March 2013.

Roy P. Zimmerman,

Director, Office of Enforcement.

[FR Doc. 2013–07469 Filed 3–29–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0053]

SHINE Medical Technologies, Inc.; Exemption

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption.

FOR FURTHER INFORMATION CONTACT: Steven Lynch, Project Manager, Research and Test Reactor Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: 301–415–1524; email: *Steven.Lynch@nrc.gov.*

SUPPLEMENTARY INFORMATION:

1.0 Background

SHINE Medical Technologies, Inc. (SHINE) intends to submit an application to construct a medical isotope production facility pursuant to the requirements in part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), and in accordance with 10 CFR 2.101(a)(5) for the purpose of producing molybdenum-99 (Mo-99). As an applicant for a permit to construct such a facility, SHINE will be subject to all applicable rules, regulations and orders of the U.S. Nuclear Regulatory Commission (NRC) now or hereafter in effect. SHINE intends to construct its medical isotope production facility in Rock County, Wisconsin.

By letter dated July 10, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12214A434), SHINE requested an interpretation of 10 CFR

2.101(a)(5), which allows an applicant for a construction permit under 10 CFR part 50 or combined operating license under 10 CFR part 52 to submit the required information of applicants by 10 CFR part 50 in two parts. However, that rule also stipulates that only production or utilization facility applicants subject to 10 CFR 51.20(b) [1] may take advantage of the two-part submittal provisions of 10 CFR 2.101(a)(5). SHINE, recognizing that not all production or utilization facilities, particularly research reactors, require an environmental impact statement or environmental impact statement supplement, requested that the NRC provide clarification on the intent of the rule. Specifically, SHINE wanted to know if production or utilization facility applicants could submit a construction permit application in two parts even if an environmental impact statement is not explicitly required for the application by 10 CFR 51.20(b).

NRC staff responded to SHINE's request in a letter dated December 7, 2012 (ADAMS Accession No. ML12319A192). In this letter, staff concluded:

> With respect to SHINE's questions regarding 10 CFR 2.101(a)(5), in order for an applicant for a construction permit under part 50 of 10 CFR to submit an application in two parts under 10 CFR 2.101(a)(5), the proposed facility must be subject to 10 CFR 51.20(b) * * * SHINE's proposed action for licensing a medical isotope production facility is not an action identified in 51.20(b); therefore, 10 CFR 2.101(a)(5) is not applicable to SHINE's licensing proposal. However, SHINE could apply for an exemption under 10 CFR 50.12 in order to submit its application for a construction permit in two parts as described in 10 CFR 2.101(a)(5).

Staff went on to say that should an exemption to 10 CFR 2.101(a)(5) be sought, the request must set forth existing special circumstances warranting the exemption, as well as provide the proposed contents of each part of the construction permit application.

2.0 Request/Action

Section 2.101(a)(5) of 10 CFR states:

> An applicant for a construction permit under part 50 of this chapter * * * for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3) or § 50.22 of this chapter * * * may submit the information required of applicants by part 50 * * * of this chapter in two parts.

[1] 10 CFR 51.20(b) enumerates the types of licensing and regulatory actions requiring an environmental impact statement or a supplement to an environmental impact statement.

SHINE's application requested an exemption from the stipulation of 10 CFR 2.101(a)(5) that applications for a construction permit under 10 CFR part 50 must be of the type requiring an environmental impact statement or a supplement to an environmental impact statement as described in 10 CFR 51.20(b). The exemption would allow SHINE to submit a portion of its construction permit up to six months prior to the submittal of the remainder of the application regardless of whether or not an environmental impact statement or a supplement to an environmental impact statement is prepared for its construction permit application. Specifically, in accordance with 10 CFR 2.101(a)(5), SHINE proposes to submit the following in part one of its construction permit application:

- The environmental report required by 10 CFR 50.30(f),
- The description and safety assessment of the site required by 10 CFR 50.34(a)(1),
- The filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21,
- The general information required by 10 CFR 50.33, and
- The agreement limiting access to Classified Information required by 10 CFR 50.37.

Part two of SHINE's construction permit application will contain the remainder of the preliminary safety analysis report required by 10 CFR 50.34(a).

3.0 Discussion

To docket SHINE's construction permit application in two parts under 10 CFR 2.101(a)(5), as proposed, an exemption to the regulations is required. Given the dependency of docketing of an application under 10 CFR 2.101(a) to an applicant meeting the requirements of 10 CFR 50.30, it is appropriate to use the requirements of 10 CFR 50.12 to evaluate this exemption request.

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. While the action requested is not for an exemption to a 10 CFR part 50 regulation, given the dependency of docketing a construction permit application in accordance with 10 CFR 2.101(a) in order to satisfy other requirements of 10 CFR Part 50, it is appropriate to evaluate this exemption using the criteria of 10 CFR 50.12.

Authorized by Law

This exemption would allow SHINE to submit its application for a 10 CFR part 50 construction permit application in two parts as provided for in 10 CFR 2.101(a)(5). The NRC staff has determined that granting of the proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

No Undue Risk to Public Health and Safety

The underlying purpose of 10 CFR 2.101(a)(5) is to provide a mechanism to facilitate the construction permit application process by allowing applicants to submit their applications for a construction permit in two parts. The provisions for two-part construction permit application submittals were added as an amendment to the regulations of 10 CFR part 2 on April 24, 1974, in the **Federal Register**. The intent of this final rule was to ''reduce the time required to bring on line nuclear power plants which satisfy all environmental and safety requirements * * * [and remove] unnecessary obstacles to the construction of power plants needed to meet the nation's energy needs'' (39 FR 14506). Recognizing the procedural nature of the amendment, the Commission made the language of the final rule effective without the customary 30-day notice. It is consistent with this reasoning that the ability for SHINE to submit its construction permit application in two parts will facilitate the licensing process of this facility in its effort to respond to the nation's demand for a domestic supply of Mo-99.

The current provisions of 10 CFR 2.101(a)(5) state that one part of the submittal must include the environmental report required by 10 CFR 50.30(f), while the other part must include the preliminary safety analysis report required by 10 CFR 50.34(a). Whichever part is submitted first must also contain the following as part of the submittal:

- The filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21,
- The general information required by 10 CFR 50.33,
- The description and safety assessment of the site required by 10 CFR 50.34(a)(1); and
- The agreement limiting access to Classified Information required by 10 CFR 50.37.

For the case where the preliminary safety analysis report required by 10

CFR 50.34(a) is submitted second, the information required by 10 CFR 50.34(a)(2)–(a)(8) does not need to accompany the first part of the submittal. Either part of the construction permit application may be submitted first as long as the submission of each part of the application does not precede or follow the other by longer than six months.

While the current language of the rule limits its applicability to applications meeting the criteria of licensing and regulatory actions requiring environmental impact statements as described in the provisions of 10 CFR 51.20(b), over time the language of the rule has been expanded to include types of applications not originally considered at the time of the initial rulemaking. For example, in 2007 the language of the rule was modified to include applicants seeking combined licenses under 10 CFR Part 52. The Commission determined that ''[t]here are no considerations unique to combined licenses which would weigh against allowing a combined license applicant to submit a two part application under paragraph (a)(5) of § 2.101'' (72 FR 49412). Similarly, given the procedural nature of this rule, there are no unique considerations for medical isotope production facilities, which would weigh against allowing a license applicant such as SHINE to submit a two-part application under 10 CFR 2.101(a)(5).

Based on the procedural nature of this request, as described above, no new accident precursors are created by allowing an applicant to submit a construction permit application in two parts; thus, the probability of postulated accidents is not increased. Also, based on the above, the consequences of postulated accidents are not increased. Therefore, there is no undue risk [2] to public health and safety.

Consistent With Common Defense and Security

As discussed above, the proposed exemption would allow SHINE to submit its application for a 10 CFR part 50 construction permit application in two parts as provided for in 10 CFR 2.101(a)(5). The timing of submitting a construction permit application has no relation to security issues. Therefore, the common defense and security is not impacted by this exemption.

Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12, are present whenever application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.[3] The underlying purpose of 10 CFR 2.101(a)(5), as discussed above, is to facilitate the application submittal process for construction permit applicants when it is in the interest of the public to remove unnecessary obstacles to meet the needs of the nation. When the rule was originally written, there was a ''deep national concern over energy sources and supply'' (39 FR 14508). Similarly, there currently exists a national concern over the sources and supply of Mo-99 in the United States. Recognizing this concern, The U.S. Department of Energy and the National Nuclear Security Administration are currently supporting four separate commercial entities in the development of low enriched uranium technologies to accelerate commercial production of Mo-99 in the United States through the Global Threat Reduction Initiative.[4] In support of this effort and in alignment with the underlying purpose of the rule, SHINE's letter requesting an exemption from the requirements of 10 CFR 2.101(a)(5) dated February 18, 2013, states that it intends to ''construct and operate a medical isotope production facility able to produce molybdenum-99'' (ADAMS Accession No. ML13051A007) in order to meet the emerging domestic demands for the Mo-99 and its decay product, technetium-99m, in nuclear medicine procedures. Therefore, since the underlying purpose of 10 CFR 2.101(a)(5) is achieved, the special circumstances required by 10 CFR 50.12 for the granting of an exemption from 10 CFR 2.101(a)(5) exist.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants SHINE Medical Technologies, Inc. an exemption from the requirement of 10 CFR 2.101(a)(5) limiting the regulation's applicability to licensing and regulatory actions requiring environmental impact statements as described in the provisions of 10 CFR 51.20(b). The granting of this exemption allows SHINE to submit the construction permit application for its medical isotope production facility in two parts in accordance with the remainder of the provisions of 10 CFR 2.101(a)(5).

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment as it is procedural in nature. Furthermore, the Commission has determined that this exemption request meets the criteria in 10 CFR 51.22(c)(25) for a licensing action that is categorically excluded from an environmental assessment because the granting of this exemption: (1) Neither involves a significant reduction in the margin of safety nor creates a possibility of an accident, thus resulting in no significant hazards consideration; (2) would not result in the release of effluents, thus resulting in no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (3) neither introduces new radiological hazards nor increases existing radiological hazards, thus resulting in no significant increase in individual or cumulative public or occupational radiation exposure; (4) would not involve construction, thus resulting in no significant construction impact; (5) would occur prior to any radiological components being in place at the facility and would not create any new accident precursors, thus resulting in no significant increase in the potential for or consequences from radiological accidents; and (6) would allow the submission of a construction permit application in two parts, which is related to a scheduling requirement and is administrative in nature in accordance with 10 CFR 51.22(c)(25)(G) and (I), respectively. This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 20th day of March, 2013.

For the Nuclear Regulatory Commission.

Lawrence E. Kokajko,

Director, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

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[2] Risk is defined as the probability of an accident multiplied by the consequences of an accident. More information on risk as it is applies to NRC regulatory activities can be found in the Commission White Paper on Risk-Informed and Performance Based Regulation, SECY–98–144.

[3] There are several ways to demonstrate the presences of special circumstances. See 10 CFR 50.12(a)(2)(i)–(vi). SHINE has proposed that the special circumstances described in 10 CFR 50.12(a)(2)(ii) are present in this circumstance.

[4] To learn more about the Global Threat Reduction Initiative and U.S. Department of Energy's support of domestic Mo-99 production, please visit *http://nnsa.energy.gov/.*