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LICENCE FOR OPERATION OF REMOTE AFTERLOADING BRACHYTHERAPY UNIT

In exercise of powers conferred under Section 16 of the Atomic Energy Act, 1962 read with Rule 3 of the Atomic Energy (Radiation Protection) Rules, 2004, the Atomic Energy Regulatory Board (AERB) hereby issues **Authorization** in favour of **SATISH RAMKRISHNA SONAWANE** to operate the following **REMOTE AFTERLOADING BRACHYTHERAPY Unit** located at **SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED, Ahmednagar** for **patient treatment** purposes.

Make	Model	Sr. No	Equipment ID	Radioisotope	No of Sources	Maximum Design Capacity
Nucletron	MicroSelectron HDR V3 (106990BNN)	20190	E-RH-057951	Ir-192	1	444 GBq

The **DIRECTOR, SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED, Ahmednagar** and **SATISH RAMKRISHNA SONAWANE** are hereby identified as the Employer and licensee respectively, for the purpose of assigning the responsibilities specified in the Atomic Energy (Radiation Protection) Rules, 2004, in respect of radiation protection of workers, public and environment because of possession and operation of the above equipment by **SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED, Ahmednagar**.

This license shall be subject to the following conditions:

1. The employer and the licensee shall ensure compliance of the provisions of
 - i)The Atomic Energy Act, 1962;
 - ii)The Atomic Energy (Radiation Protection) Rules, 2004;
 - iii)The Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987;
 - iv)All applicable Safety Codes, Guides on Safety and Security issued by AERB for the above practice and directives/other applicable regulatory documents issued by AERB from time to time.
2. It shall further be ensured that:
 - a)The functional performance of the equipment is satisfactory during its useful life from radiological safety view point.
 - b)Any incident involving radiation source(s) or loss / theft of source(s) is reported promptly within 24 hours of occurrence to AERB. In the event of the loss / theft of source(s), appropriate law enforcement authority shall be contacted immediately.
 - c)Disposal of all disused radiation sources are carried out in accordance with the procedures laid down by AERB.
 - d)The terms and conditions stated in Annexure-1 are complied with.



3. This Licence may be suspended, modified or withdrawn as deemed fit in the event of contravention of the provisions of the above Act / Rules / Codes or terms and conditions of issuance.

4. A copy of this Licence shall be available at the place where the radiation sources are being operated / stored.

This is computer generated copy. Hence no signature required.

Dr. P. K. Dash Sharma
Head, RSD
(Issuing Authority)

SATISH RAMKRISHNA SONAWANE
SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED
PDVVPFS MEDICAL COLLEGE AND HOSPITAL, Ahmednagar, Maharashtra-414111

CopyTo:DIRECTOR,SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED,Ahmednagar

अनुबंध Appendix-1

नियम और शर्तें TERMS AND CONDITIONS

1. **विकिरण स्रोतों के संचालन पर प्रतिबंध Constraints on operation of radiation sources:** लाइसेंसधारक किसी भी विकिरण स्रोत (रेडियोधर्मी स्रोत और/या विकिरण उत्पन्न करने वाला उपकरण) को नहीं संभालेगा (क) लाइसेंस में विनिर्दिष्ट के अलावा; (ख) लाइसेंस में विनिर्दिष्ट के अलावा किसी अन्य उद्देश्य के लिए; और (ग) लाइसेंस में विनिर्दिष्ट के अलावा किसी भी स्थान पर। The licensee shall not handle any radiation source (Radioactive Sources and/or Radiation Generating Equipment): (a) other than those specified in the licence; (b) for any purpose other than those specified in the licence; and (c) in any location except as specified in the licence.
2. **उत्तरदायित्व Responsibilities:** परमाणु ऊर्जा (विकिरण संरक्षण) नियम, 2004 में निर्दिष्ट नियोक्ता, लाइसेंसधारक, आरएसओ और श्रमिकों की जिम्मेदारियों का पालन किया जाएगा। विकिरण फैसिलिटी/गतिविधियों की सुरक्षा के लिए मुख्य जिम्मेदारी लाइसेंसधारक की होगी और नियामक संस्था द्वारा कोई भी नियामक गतिविधियां या निरीक्षण लाइसेंसधारक को सुरक्षा के लिए उसकी जिम्मेदारी से मुक्त नहीं करता है। The responsibilities of the employer, licensee, RSO and workers as specified in the Atomic Energy (Radiation Protection) Rules, 2004 shall be complied with. Prime responsibility for the safety of the radiation facility/activities shall lie with the licensee and any regulatory activities or inspections by the regulatory body does not relieve the licensee from his/her responsibility for safety.
3. **स्रोतों की सलामती और सुरक्षा Safety and Security of sources:** विकिरण स्रोत की सलामती और सुरक्षा हर समय अर्थात् खरीद से लेकर विकिरण स्रोत के निपटान/उपकरण के बंद होने तक सुनिश्चित की जाएगी। रेडियोधर्मी स्रोत/रेडियोधर्मी स्रोतों को रखने वाले उपकरण अस्थाई रूप से उपयोग में नहीं होने पर एक अनुमोदित और सुरक्षित भंडारण कक्ष में संग्रहीत किए जाएंगे। The safety and security of the radiation source shall be ensured at all the times i.e. from procurement up to the time of disposal of the radiation source/decommissioning of the equipment. The equipment housing the radioactive source/radioactive sources shall be stored in an approved and secured storage room when temporarily not in use.
4. **नियामक सिफारिशें Regulatory Recommendations:** रेडियोधर्मी स्रोतों के लिए विकिरण सुरक्षा उपायों और भौतिक सुरक्षा उपायों के संबंध में सक्षम प्राधिकारी द्वारा समय-समय पर जारी की जाने वाली सभी नियामक सिफारिशों को लागू किया जाएगा और इसका अक्षरशः पालन किया जाएगा। All the regulatory recommendations, as may be issued from time to time, by the Competent Authority in respect of radiation safety measures and physical security measures for radioactive sources shall be implemented and followed in its letter and spirit.
5. **अर्हताप्राप्त कार्मिक Qualified manpower:** उपकरण/स्रोतों का संचालन आईआरबी को सूचित किए गए योग्य और प्रशिक्षित विकिरण कर्मियों द्वारा किया जाएगा। Equipment/sources shall be operated by qualified and trained radiation workers as intimated to AERB.
6. **ले-आउट का संशोधन Modification of layout:** आईआरबी के पूर्वानुमोदन के बिना स्थापना/स्रोत भंडारण फैसिलिटी के अनुमोदित लेआउट में संशोधन, जिसमें विकिरण सुरक्षा निहितार्थ हो सकते हैं, नहीं किए जाएंगे। Modifications in the approved layout of the installation/source storage facility that may have radiation safety implications shall not be carried out without obtaining prior approval of AERB.
7. **विकिरण निगरानी Radiation Surveillance:** विकिरण कार्य में लगे व्यक्ति (व्यक्तियों) की विकिरण निगरानी (कार्मिक निगरानी सेवा) नियामक आवश्यकताओं के अनुसार प्रदान की जाएगी। Radiation Surveillance (personnel Monitoring Service) of person(s) engaged in radiation work shall be provided as per the regulatory requirements.
8. **आवधिक सुरक्षा स्थिति रिपोर्ट Periodic Safety Status Report:** संस्थान के पास मौजूद सभी विकिरण उपकरणों/स्रोतों की आवधिक स्थिति रिपोर्ट वर्ष में एक बार (कम से कम) आईआरबी को प्रस्तुत की जाएगी। The periodic status report of

all radiation devices/sources in the possession of the institution shall be submitted (at least) once in a year to AERB.

9. **रखरखाव Maintenance**: उपकरणों का रखरखाव संबंधित आईआरबी संरक्षा कोड, गाइड और वर्तमान में लागू मानकों के अनुसार किया जाएगा। Maintenance of the equipment shall be carried out in accordance with the respective AERB safety code, guide and standards currently in force.
10. **बिक्री या स्थानांतरण Sale or transfer**: विकिरण स्रोत/डिवाइस/उपकरण/रेडियोधर्मी अपशिष्ट आईआरबी से पूर्वानुमोदन प्राप्त किए बिना किसी अन्य व्यक्ति को बेचा या अन्यथा हस्तांतरित नहीं किया जाएगा। The radiation source/device/equipment/radioactive waste shall not be sold or otherwise transferred to another person without obtaining prior approval from AERB.
11. **विकिरण स्रोतों का संचलन Movement of radiation source**: विकिरण उपकरण/स्रोतों को आईआरबी से पूर्वानुमोदन प्राप्त किए बिना, परिसर के भीतर (जब तक कि उपकरण परिसर के भीतर नियमित आवाजाही के लिए न हो) या बाहर एक स्थान से दूसरे स्थान पर नहीं ले जाया जाएगा। The radiation equipment/sources shall not be moved from one location to another, within the premises (unless the equipment is meant for routine movement within the premises) or outside, without obtaining prior approval from AERB.
12. **रेडियोधर्मी स्रोत का परिवहन Shipment of radioactive material**: रेडियोधर्मी सामग्री का परिवहन : आईआरबी से परिवहन के लिए पूर्वानुमति प्राप्त की जाएगी। यह सुनिश्चित किया जाएगा कि रेडियोधर्मी सामग्री के सुरक्षित परिवहन के लिए राष्ट्रीय/ अंतर्राष्ट्रीय विनियमों के अनुसार योग्य पैकिंग, चिह्नित और लेबलिंग किया जाता है। Prior approval for shipment shall be obtained from AERB. The package containing radioactive material is properly packed, marked and labelled and the shipment of radioactive material is in accordance with national/international regulations for safe transport of radioactive material.
13. **नियामक निरीक्षण Regulatory inspection**: विकिरण फैसिलिटी का निरीक्षण करने के लिए सक्षम प्राधिकारी के प्राधिकृत प्रतिनिधि (प्रतिनिधियों) को पूर्ण सहयोग दिया जाएगा। Full co-operation shall be accorded to authorized representative(s) of the Competent Authority to inspect radiation facility.
14. **अप्रयुक्त विकिरण स्रोतों तथा रेडियोधर्मी अपशिष्ट का प्रबंधन Management of disused radiation sources and radioactive waste**: जब कोई विकिरण स्रोत अब अधिकृत उद्देश्य के लिए उपयोग में नहीं है, या इसके उपयोगी जीवन के पूरा होने पर, उपकरण को बंद कर दिया जाएगा और रेडियोधर्मी स्रोत आईआरबी द्वारा निर्धारित प्रक्रिया के अनुसार संरक्षित प्रबंधन के लिए मूल आपूर्तिकर्ता को वापस कर दिया जाएगा। आयातित रेडियोधर्मी स्रोतों के संबंध में, उनके निर्यात के लिए आईआरबी से पूर्व अनुमति प्राप्त की जाएगी। When a radiation source is no longer in use for the authorized purpose, or upon completion of its useful life, the equipment shall be decommissioned and radioactive source shall be returned to the original supplier for safe management in accordance with the procedure laid down by AERB. In respect of imported radioactive sources, prior permission for export of the same shall be obtained from AERB.
15. **असामान्य घटनाओं की रिपोर्ट Reporting of unusual occurrences**: यदि विकिरण स्रोत/उपकरण की संरक्षा और सुरक्षा से जुड़ी कोई घटना होती है, तो घटना होने के 24 घंटे के भीतर आईआरबी को इसकी सूचना दी जाएगी। स्रोत के खो जाने या चोरी होने की स्थिति में, मामले की सूचना तत्काल इलाके में उपयुक्त कानून एवं प्रवर्तन एजेंस को दी जाएगी। If an incident involving the safety of radiation equipment/device/source and security of the radiation source occurs, the same shall be intimated to AERB within 24 hours of the occurrence of the incident. In the event of loss or theft of the source, the matter shall also be promptly reported to the appropriate law enforcement agency in the locality.
16. **रेडियोधर्मी अपशिष्ट के निपटान के लिए संचालन/प्राधिकरण के लिए लाइसेंस में संशोधन Amendment of licence for operation/Authorization for disposal of radioactive waste**: इस लाइसेंस/प्राधिकरण में निहित जानकारी में कोई भी परिवर्तन, इसके जारी होने के बाद (लाइसेंसधारक, नियोक्ता, संस्थान का नाम, पता आदि के रूप में) आईआरबी को सूचित किया जाएगा और इस संबंध में इस लाइसेंस के लिए उपयुक्त आवश्यक संशोधन सक्षम प्राधिकारी, आईआरबी से प्राप्त किया जाएगा। Any change in the information contained in this licence/authorization, after its issuance (as

change of licensee, employer, name of institution, address etc.), shall be intimated to the AERB and appropriate necessary amendment to this effect to this licence shall be obtained from the Competent Authority, AERB

17. **लाइसेंस के नियमों और शर्तों में संशोधन Modification of the terms and conditions of the licence:** लाइसेंस के नियमों और शर्तों को सुरक्षा के हित में सक्षम प्राधिकारी द्वारा आवश्यक समझे जाने पर संशोधित, पुनरीक्षित या सुधार किया जा सकता है। The terms and conditions, of the licence can be amended, revised or modified, as considered necessary by the Competent Authority in the interest of safety.
18. **लाइसेंस का नवीनीकरण Renewal of licence:** लाइसेंस का नवीनीकरण इसकी समाप्ति की तारीख से पहले सक्षम प्राधिकारी से प्राप्त किया जाएगा। लाइसेंस के गैर-नवीनीकरण से लाइसेंसधारक को कब्जे के तहत विकिरण स्रोतों की सलामति एवं सुरक्षा की जिम्मेदारी से तब तक मुक्त नहीं किया जाता है जब तक कि उपकरण बंद नहीं किया जाता है/और सुरक्षित प्रबंधन के लिए मूल आपूर्तिकर्ता को रेडियोधर्मी स्रोत वापस नहीं किया जाता है। आईआरबी द्वारा आवेदनों के प्रसंस्करण के लिए अग्रणी समय को ध्यान में रखते हुए लाइसेंस के नवीनीकरण के लिए आवेदन आईआरबी को समीक्षा के लिए अग्रिम रूप से प्रस्तुत किया जाएगा। लाइसेंस की समाप्ति के दो महीन पहले लाइसेंसधारक द्वारा नवीनीकरण के लिए आवेदन प्रस्तुत किया जा सकता है। Renewal of licence shall be obtained from the Competent Authority prior to its date of expiry. Non-renewal of licence does not absolve the licensee from the responsibility of safety and security of radiation sources under possession till the equipment is decommissioned /and radioactive source is returned to the original supplier for safe management. Application for renewal of this licence shall be submitted to AERB for review well in advance, taking into account the lead time for processing of the applications by AERB. Application for renewal may be submitted by the licensee two months prior to expiry of the licence.
19. **डीकमीशनन के लिए वित्तीय प्रावधान Financial provision for decommissioning:** लाइसेंसधारक यह सुनिश्चित करेगा कि एक बार उपयोग में आने के बाद विकिरण स्रोतों के सुरक्षित प्रबंधन के लिए उचित वित्तीय प्रावधानों सहित व्यवस्था की जाती है। वित्तीय प्रावधान की सीमा का निर्धारण विकिरण स्रोत के आपूर्तिकर्ता/निर्माता के परामर्श से किया जाएगा। वित्तीय प्रावधान सामान्य परिदृश्य के साथ-साथ दिवालियापन या अन्य बाधाओं का सामना करने वाली असंभावित घटनाओं को ध्यान में रखते हुए किया जाएगा। Licensee shall ensure that arrangements, including appropriate financial provisions, are made for the safe management of radiation sources, once it ceases to be in use. The extent of financial provision shall be arrived at in consultation with the supplier/manufacturer of the radiation source. The financial provision shall be made with due consideration to normal scenario as well as unlikely events like bankruptcy or other constraints that may be encountered.
20. **अपराध और दंड Offences and Penalties:** यदि लाइसेंस/प्राधिकरण की शर्तों और अन्य निर्धारित विनियामक प्रावधानों का उल्लंघन किया जाता है तो परमाणु ऊर्जा (विकिरण संरक्षण) नियम, 2004 और परमाणु ऊर्जा (रेडियोधर्मी अपशिष्ट का सुरक्षित निपटान) नियम 1987 में निर्दिष्ट शर्तों के अनुसार आईआरबी द्वारा लाइसेंस/प्राधिकार को निलंबित, संशोधित या वापस लिया जा सकता है। जहां उपयुक्त समझा जाए, किए गए अपराध के विरुद्ध परमाणु ऊर्जा अधिनियम, 1962 में प्रावधान के अनुसार आईआरबी संस्था द्वारा दंडात्मक कार्रवाई शुरू की जा सकती है। Licence/authorisation can be suspended, modified or withdrawn by AERB, as specified in the Atomic Energy (Radiation Protection) Rules, 2004 and Atomic Energy (Safe Disposal of Radioactive Wastes) Rules 1987 if any of the terms and conditions of the licence/authorisation and other stipulated regulatory provisions is/are contravened. Where deemed appropriate, AERB may initiate penal action against an offence committed by the institution, as provided in the Atomic Energy Act, 1962.

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नोट Note: प्रैक्टिस विशिष्ट आवश्यकताओं पर मार्गदर्शन के लिए कृपया ई-लोरा दिशानिर्देश और आईआरबी वेबसाइट

www.aerb.gov.in देखें। For guidance on practice specific requirements, please refer e-LORA guidelines and AERB website www.aerb.gov.in



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Valid Till: 05/04/2027

LICENCE FOR OPERATION OF MEDICAL ACCELERATOR UNIT

In exercise of powers conferred under Section 16 and 17 as applicable of the Atomic Energy Act, 1962 read with Rule 3 of the Atomic Energy (Radiation Protection) Rules, 2004, the Atomic Energy Regulatory Board (AERB) hereby issues **licence** in favour of **SATISH RAMKRISHNA SONAWANE** to operate the following **MEDICAL ACCELERATOR** unit located at **SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED, Ahmednagar** for **patient treatment** purposes.

Make	Model	Sr. No	Equipment ID	Photon energy(ies) (MV)	Electron energy(ies) (MeV)
Elekta	Synergy Platform	153813	G-RA-057805	6,15,10	6,8,10,12,15,4

The **DIRECTOR, SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED, Ahmednagar** and **SATISH RAMKRISHNA SONAWANE** are hereby identified as the Employer and licensee respectively, for the purpose of assigning the responsibilities specified in the Atomic Energy (Radiation Protection) Rules, 2004, in respect of radiation protection of workers, public and environment because of possession and operation of the above equipment by **SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED, Ahmednagar**.

This license shall be subject to the following conditions:

- The employer and the licensee shall ensure compliance of the provisions of
 - The Atomic Energy Act, 1962;
 - The Atomic Energy (Radiation Protection) Rules, 2004;
 - The Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987;
 - All applicable Safety Codes, Guides on Safety and Security issued by AERB for the above practice and directives/other applicable regulatory documents issued by AERB from time to time.
- It shall further be ensured that:
 - The functional performance of the equipment is satisfactory during its useful life from radiological safety view point.
 - Any incident involving radiation source(s) or loss / theft of source(s) is reported promptly within 24 hours of occurrence to AERB. In the event of the loss / theft of source(s), appropriate law enforcement authority shall be contacted immediately.
 - Disposal of all disused radiation sources are carried out in accordance with the procedures laid down by AERB.
 - The terms and conditions stated in Annexure-1 are complied with.



3. This Licence may be suspended, modified or withdrawn as deemed fit in the event of contravention of the provisions of the above Act / Rules / Codes or terms and conditions of issuance.

4. A copy of this Licence shall be available at the place where the radiation sources are being operated / stored.

This is computer generated copy. Hence no signature required.

Dr. P. K. Dash Sharma
Head, RSD
(Issuing Authority)

SATISH RAMKRISHNA SONAWANE
SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED
PDVVPFS MEDICAL COLLEGE AND HOSPITAL, Ahmednagar, Maharashtra-414111

Copy To: DIRECTOR, SAI CANCER AND RESEARCH SERVICES PRIVATE LIMITED, Ahmednagar

Annexure-1

TERMS AND CONDITIONS OF LICENCE

1. **Operation of the Radiation Sources:** The Radiation Sources (Radioactive Sources and/or Radiation Generating Equipment) shall not be used for purposes other than that specified in the licence.
2. **Responsibilities of employer, licensee and RSO:** The regulatory responsibilities of the employer, licensee and the RSO are laid down in the Atomic Energy (Radiation Protection) Rules, 2004. If the licensee or the RSO leaves the institution or is transferred to another department of the same institution or ceases to be in a position to discharge their duties in respect of the radiation sources in the institution, the same should be brought to the notice of AERB through a written communication.
3. **Responsibility of safety and the security of the source:** The safety and security of the radiation source shall be the responsibility of the employer from procurement up to the time of disposal of the source.
4. **Regulatory recommendations:** All the regulatory requirements, as may be notified from time to time, by the Competent Authority in respect of radiation safety measures and physical security measures shall be implemented and followed in its letter and spirit.
5. **Modification of approved layout:** Modification of the approved layout of the installation/source storage facility shall not be carried out, without obtaining prior approval of AERB
6. **Regulatory Inspection:** Full co-operation shall be accorded to authorised representative(s) of the Competent Authority to inspect radiation facility at any time.
7. **Radiation surveillance and medical surveillance:** Radiation Surveillance (personnel Monitoring Service) and medical surveillance of person(s) engaged in radiation work should be provided as required by the Competent Authority.
8. **Periodic Status Report:** The periodic status report of all radiation devices/sources in the possession of the institution shall be submitted to AERB.
9. **Storage of source not in Use:** In case of mobile equipment, the equipment housing the radioactive source should be stored in an authorized and secured storage room when not in use.
10. **Sale or transfer:** The radiation source/device/equipment shall not be sold or otherwise transferred to another person without obtaining prior approval from AERB.
11. **Movement of radiation source from one site to another:** The radiation equipment/sources shall not be moved from one location to another, within the premises or outside, without obtaining prior approval from AERB.
12. **Transport of the radiation source:** It shall be ensured that equipment housing radioactive source is packed, labeled, marked and transported in accordance with the applicable regulations for the safe transport of radioactive material, with prior approval of AERB.
13. **Disused sources:** When a radioactive source is no longer in use for the authorized purpose, or upon completion of its useful life, the source should be returned to the original supplier, in accordance with the procedure for the same laid down by AERB. In respect of imported radioactive sources, prior permission for re-export of the same shall be obtained from AERB.
14. **Reporting of unusual occurrences:** If an incident involving the safety and / or security of the radiation source occurs, the same shall be intimated to AERB within 24 hours of the occurrence of the incident. In the event of loss or theft of the source, the matter shall also be reported to the local police authorities at least within 24 hours of occurrence of the incident.
15. **Renewal of Licence:** Renewal of license shall be obtained from the Competent Authority prior to its date of expiry.
16. **Amendment to Licence:** Any change in the information contained in this licence, after its issuance (as change of Licensee, Employer, name of institution, address etc.), shall be intimated to the AERB and appropriate necessary amendment to this effect to this licence is obtained from the Competent Authority, AERB.
17. **Offences and penalties:** This License can be suspended, modified or withdrawn by AERB, as specified in the Atomic Energy (Radiation Protection) Rules, 2004, if any of the terms and conditions of the license and other stipulated regulatory provisions is/are contravened. Where deemed appropriate, AERB may initiate penal action against the concerned institution in the event of offences, as provided in the Atomic Energy Act, 1962.