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The Gazette of India

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PART II—Section 3—Sub-section (I)

प्रकाशक से प्राप्तिकृत
PUBLISHED BY AUTHORITY

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No. 11] NEW DELHI, TUESDAY, JANUARY 10, 2006/PAUSA 20, 1927

परमाणु उर्जा विभाग
शुद्धिपत्र
मुम्बई, 5 जानवरी, 2006

सा.का.मि. 11(अ).— भारत के राजपत्र के भाग-II, खंड 3 (I) में सा.का.मि. 303 के अंतर्गत
dिनांक 11सितंबर 2004 को प्रकाशित दिनांक 25.08.2004 की अधिसूचना सं.
ईए/30(1)/2002-ईआर में, साध में दिए गए सल्लानक में समाहित सुधार करने हेतु प्राधिकृत
kिया जाता है।

[भा. सं. ईए/30(1)/2002-ईआर]

व्रो. पी. राजा, अपर सचिव (उद्योग एवं खनिज)

सल्लानक

(भारत के राजपत्र के भाग-II, खंड 3 (I) में दिनांक 11सितंबर 2004 को प्रकाशित)

परमाणु उर्जा (विकिरण संरक्षण) नियम, 2004 (ईआरएपीआर, 2004) हेतु शुद्धिपत्र।

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<td>01</td>
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<td>&quot;ये सरकारी राजपत्र में अपने प्रकाशन की तारीख से प्रवृत्त होंगे।&quot;</td>
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<td>02</td>
<td>नियम 2(1) (t)</td>
<td>शब्दावली और वाक्यांश &quot;ऐसे खोतों से उद्भासन अथवा होने वाले उद्भासन को कम करने।&quot;</td>
<td>&quot;ऐसे खोतों से उद्भासन अथवा होने वाले उद्भासन को कम करने।&quot;</td>
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<td>03</td>
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<td>&quot;विकिरण प्रतिविद्यमान का विकिरण संरक्षण नहीं करेगा।&quot;</td>
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<td>04</td>
<td>&quot;लाइसेंस&quot; नियम 3(3)</td>
<td>कोई भी लाइसेंस निर्माणित संक्रियाओं से सम्बन्धित खोतों और प्रक्रियाओं के लिए दिया जाएगा।</td>
<td>कोई भी लाइसेंस - (क) निर्माणित संक्रियाओं से सम्बन्धित खोतों और प्रक्रियाओं के लिए दिया जाएगा।</td>
</tr>
</tbody>
</table>
(i) नामिकीय ईशान चक्र सुविधाएँ;
(ii) गामा किरण प्रकोष्ठों से इतर भूल आधारित उच्च प्रबलता वाले गामा किरणक;
(iii) अनुसंधान और ओधोरिक अनुप्रयोग के लिए उपयोग किए जाने वाले कण त्वरक;
(iv) न्यूट्रॉन जनित्र;
(v) रेडियोसिक्रिय सामग्री अथवा विकिरण प्रजनन उपकरणों के वाणिज्यिक उत्पादन में कार्यरत सुविधाएँ;
(vi) रेडियोग्रेफी में उपयोग किए जाने वाले टेलिग्राम और त्वरक;
(vii) संगमित टोमोग्राफी (सीटी)-यूनिट;
(viii) माध्यमी विकिरण चिकित्सात्मक एक्स-रे यूनिट;
(ix) ओधोरिक रेडियोग्राफी;
(x) सक्षम प्राधिकारी द्वारा समय-समय पर अधिसूचित ऐसे अन्य लोट अथवा प्रक्रियाएँ.
बशति कि -

(i) ब्रेकीथेरपी;
(ii) गहन एक्स-रे यूनिट, ऊपरी और संपर्वी थेरेपी एक्स-रे यूनिट;
(iii) गामा किरण प्रकोष्ठ;
(iv) नामिकीय औषध सुविधाएँ;
(v) रेडियोसिक्रिय सामग्री युक्त न्यूक्लिऑनिक गेजों और उपभोक्ता उपाधि के वाणिज्यिक उत्पादन एवं कार्यरत सुविधाएँ;
(vi) सक्षम प्राधिकारी द्वारा समय-समय पर अधिसूचित किए जाने वाले अन्य लोट अथवा प्रक्रियाएँ;

की संक्रिया से समद्ध लोटों और प्रक्रियाओं के लिए प्राधिकृत किया जाना आवश्यक है.
वर्तमान यह भी कि --

(i) थेरेशी सिम्युलेटर सहित चिकित्सा नैदानिक एक्स-रे उपकरण;
(ii) अनुसंधान के लिए प्रयोग किए जाने वाले विश्लेषणात्मक एक्स-रे उपकरण;
(iii) न्यूक्लियॉनिक रेडियोसर्क्रिय चोट;
(iv) आरआईए प्रयोगशालाएँ;
(v) अनुरोधलेख अध्ययनों में रेडियोसर्क्रिय चोट;
(vi) रेडियोसर्क्रिय सामग्री के प्रयोग द्वारा जैव-चिकित्सा अनुसंधान; और
(vii) सक्षम प्राधिकरण द्वारा समय-समय पर अथवा निर्देशित किए जाने वाले अन्य सीट अथवा प्रक्रियाओं;

की संख्या से समबंधित चोटों और प्रक्रियाओं के लिए पंजीकरण आवश्यक है।

बसते यह भी कि --

(i) विकिरण प्रतिष्ठापन के स्थल निर्माण, अभिकल्पन, निर्माण, कमीशन और डिक्लीर निर्माण के लिए अनुमोदन;
(ii) विनिर्माण और आपूर्ति के प्रयोजनार्थ सीलबंद छोटों, विकिरण प्रवाह प्राप्तवर्ष और रेडियोसर्क्रिय छोटों से युक्त उपकरण के लिए अनुमोदन;
(iii) रेडियोसर्क्रिय सामग्री के परिवहन हेतु पैकेज डिजाइन के लिए अनुमोदन;
(iv) रेडियोसर्क्रिय छोटों की नौ-परिवहन संस्थीकृति के लिए अनुमोदन;

वर्तमान यह भी कि --

(घ) निम्नलिखित की संख्या से समबंधित चोटों और प्रक्रियाओं के लिए पंजीकरण आवश्यक होगा --

(i) थेरेशी सिम्युलेटर सहित चिकित्सा नैदानिक एक्स-रे उपकरण;
(ii) अनुसंधान के लिए प्रयोग किए जाने वाले विश्लेषणात्मक एक्स-रे उपकरण;
(iii) न्यूक्लियॉनिक रेडियोसर्क्रिय चोट;
(iv) आरआईए प्रयोगशालाएँ;
(v) अनुरोधलेख अध्ययनों में रेडियोसर्क्रिय चोट;
(vi) रेडियोसर्क्रिय सामग्री के प्रयोग द्वारा जैव-चिकित्सा अनुसंधान; और
(vii) सक्षम प्राधिकरण द्वारा समय-समय पर अथवा निर्देशित किए जाने वाले अन्य सीट अथवा प्रक्रियाओं;

बसते यह भी कि --

(घ) निम्नलिखित हेतु सहमति लेना आवश्यक होगा --

(i) विकिरण प्रतिष्ठापन के स्थल निर्माण, अभिकल्पन, निर्माण, कमीशन और डिक्लीर निर्माण के लिए अनुमोदन;
(ii) विनिर्माण और आपूर्ति के प्रयोजनार्थ सीलबंद छोटों, विकिरण प्रवाह प्राप्तवर्ष और रेडियोसर्क्रिय छोटों से युक्त उपकरण के लिए अनुमोदन;
(iii) रेडियोसर्क्रिय सामग्री के परिवहन हेतु पैकेज डिजाइन के लिए अनुमोदन;
(iv) रेडियोसर्क्रिय छोटों की नौ-परिवहन संस्थीकृति के लिए अनुमोदन;
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<th>नियम</th>
<th>कार्य</th>
<th>परिवर्तन संस्थीकृति के लिए अनुमोदन; और</th>
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| 05    | नियम 7(1) | शास्त्रीली और वाक्यांश "किसी लाइसेंस के लिए नियोजक अथवा उसके द्वारा विभिन्न प्राधिकृत किए गए व्यक्ति द्वारा शक्ति द्वारा सक्षम प्राधिकार को आवेदन प्रस्तुत किया जाए।" | "किसी लाइसेंस के लिए नियोजक अथवा उसके द्वारा विभिन्न प्राधिकृत किए गए व्यक्ति द्वारा सक्षम प्राधिकार को आवेदन प्रस्तुत किया जाएगा।"
| 06    | नियम 10(i) | शास्त्रीली और वाक्यांश "की राय में यदि लाइसेंससंबंधी इन नियमों के प्राधिकृतों में से किसी का भी उल्लंघन किया है।" | "की राय में यदि लाइसेंससंबंधी इन नियमों के प्राधिकृतों में से किसी का भी उल्लंघन किया है।"
| 07    | नियम 12     | शास्त्रीली और वाक्यांश "सोचों के उपयोग पर निबंधन :- (क) लाइसेंससंबंधी किसी भी ऐसे चोट को।" | "सोचों के उपयोग पर निबंधन :- (1) लाइसेंससंबंधी किसी भी ऐसे चोट को।"
| 08    | नियम 23(1)  | शब्द "जानबूझ कर" | "जानबूझ कर"
| 09    | नियम 24(2)  | शास्त्रीली और वाक्यांश "ऐसे रिकार्ड प्रतिपक्ष कर्मकार के कार्यकाल के दौरान, और उसके बाद तब तक जल्द कि कर्मकार 75 वर्ष की आयु प्राप्त करने वाला अधिकारी को तैयार कर दिया जाए। व्यक्ति अद्वितियता संबंधी कार्य को रहा कर दिया जाना के बाद कम-से-कम 30 वर्ष, जो भी बाद में घटित हो, सुरक्षित रखी जाएगी।" | "प्रत्येक कर्मकार के संबंध में ऐसे रिकार्ड उसके कार्यकाल के दौरान और उसके बाद उस कार्यकाल के लिए सुरक्षित रखे जाएंगे जब बाद कि कर्मकार ने प्रत्यक्ष वर्ष की आयु पूरी न कर ली हो या पूरी न कर ली होती या उसके व्यक्तिगत उद्देश्य संबंधी कार्य के समाप्त होने के बाद से कम-से-कम तीन वर्ष पूरे न हो चुके हों।"
| 10    | नियम 30(6) (क) (i) | शास्त्रीली और वाक्यांश "ये अभिलक्षण के आशय के अनुसार कार्य कर रहे हैं।" | "ये अभिलक्षण के आशय के अनुसार कार्य कर रहे हैं।"
| 11    | नियम 33 (4)  | शास्त्रीली और वाक्यांश "द्वारा शासित विकिरण प्रतिष्ठापनों।" | "द्वारा शासित विकिरण प्रतिष्ठापनों।"
| 12    | नियम 33 (33 दोबारा छप गया है) | शास्त्रीली और वाक्यांश "33.विकिरण प्रतिष्ठापन का डिक्शनरी।" | "34. विकिरण प्रतिष्ठापन का डिक्शनरी।"
DEPARTMENT OF ATOMIC ENERGY
CORRIGENDUM
Mumbai, the 5th January, 2006

G.S.R. 11(E).—In the Notification No.AEA/30(1)/2002-ER dated 25.8.2004
published in the Gazette of India Part-II, Section 3(i) under GSR.303 dated September
11, 2004, corrections as contained in the Annex hereto are authorised.

[F. No. AEA/30(1)/2002-ER]
V. P. RAJA, Addl. Secy. (I&M)

ANNEX

CORRIGENDUM TO THE ATOMIC ENERGY (RADIATION PROTECTION) RULES, 2004
(published as GSR 303 in the Gazette of India, Part -II, Section 3(i) dated September 11, 2004)

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<tr>
<td>01</td>
<td>Rule 1 (1)(4)</td>
<td>the words and phrases “They shall come into force from the date of their final publication in the Official Gazette”</td>
<td>“They shall come into force from the date of their publication in the Official Gazette”</td>
</tr>
<tr>
<td>02</td>
<td>Rule 2(1) k</td>
<td>the words and phrases &quot;removal or containment or radioactive materials&quot;</td>
<td>&quot;removal or containment of radioactive materials&quot;</td>
</tr>
</tbody>
</table>
| 03     | Rule 3(3) on “Licence” | A licence shall be issued for sources and practices associated with the operation of-
(i) nuclear fuel cycle facilities;
(ii) land based high intensity gamma irradiators other than gamma radiation chambers;
(iii) particle accelerators used for research and industrial applications;
(iv) neutron generators;
(v) facilities engaged in the commercial production of radioactive material or radiation generating equipment;
(vi) telegamma and accelerators used in radiotherapy;
(vii) computed tomography (CT) unit;
(viii) interventional radiological x-ray unit;
(ix) industrial radiography; and
(x) such other source or practice as may be notified by the competent authority, from time to time. | A licence shall be issued
(a) for sources and practices associated with the operation of-
(i) nuclear fuel cycle facilities;
(ii) land based high intensity gamma irradiators other than gamma radiation chambers;
(iii) particle accelerators used for research and industrial applications;
(iv) neutron generators;
(v) facilities engaged in the commercial production of radioactive material or radiation generating equipment;
(vi) telegamma and accelerators used in radiotherapy;
(vii) computed tomography (CT) unit;
(viii) interventional radiological x-ray unit;
(ix) industrial radiography; |
Provided that for sources and practices associated with the operation of—

(i) brachytherapy;
(ii) deep x-ray units, superficial and contact therapy x-ray units;
(iii) gamma irradiation chambers;
(iv) nuclear medicine facilities;
(v) facilities engaged in the commercial production of nucleonic gauges and consumer products containing radioactive material; and
(vi) such other source or practice as may be notified by the competent authority, from time to time; an authorisation shall be necessary.

Provided further that for sources and practices associated with the operation of—

(i) medical diagnostic x-ray equipment including therapy simulator;
(ii) analytical x-ray equipment used for research;
(iii) nucleonic gauges;
(iv) RIA laboratories;
(v) radioactive sources in tracer studies;
(vi) biomedical research using radioactive material; and
(vii) such other source or practice as may be notified by the competent authority, from time to time; a registration shall be necessary.

Provided also that for—

(i) approval for siting, design, construction, commissioning and decommissioning of a radiation installation;
(ii) approval for sealed sources, radiation generating equipment and equipment containing and
(x) such other source or practice as may be notified by the competent authority, from time to time.

Provided that

(b) for sources and practices associated with the operation of—

(i) brachytherapy;
(ii) deep x-ray units, superficial and contact therapy x-ray units;
(iii) gamma irradiation chambers;
(iv) nuclear medicine facilities;
(v) facilities engaged in the commercial production of nucleonic gauges and consumer products containing radioactive material; and
(vi) such other source or practice as may be notified by the competent authority, from time to time; an authorisation shall be necessary.

Provided further that

(c) for sources and practices associated with the operation of—

(i) medical diagnostic x-ray equipment including therapy simulator;
(ii) analytical x-ray equipment used for research;
(iii) nucleonic gauges;
(iv) RIA laboratories;
(v) radioactive sources in tracer studies;
(vi) biomedical research using radioactive material; and
(vii) such other source or practice as may be notified by the competent authority, from time to time;
radioactive sources, for the purposes of manufacture and supply;
(iii) approval for package design for transport of radioactive material;
(iv) approval for shipment approval for radioactive consignments; and
(v) such other source or practice as may be notified by the competent authority, from time to time;
consent shall be necessary.

Provided also that
(d) for -
(i) approval for siting, design, construction, commissioning and decommissioning of a radiation installation;
(ii) approval for sealed sources, radiation generating equipment and equipment containing radioactive sources, for the purposes of manufacture and supply;
(iii) approval for package design for transport of radioactive material;
(iv) approval for shipment approval for radioactive consignments; and
(v) such other source or practice as may be notified by the competent authority, from time to time;
consent shall be necessary.

<table>
<thead>
<tr>
<th>No.</th>
<th>Rule</th>
<th>Text</th>
<th>Modified Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>04</td>
<td>Rule 7(1)</td>
<td>the words and phrases &quot;An application for licence shall be made by to the competent authority ....&quot;</td>
<td>&quot;An application for licence shall be made by to the competent authority ....&quot;</td>
</tr>
<tr>
<td>05</td>
<td>Rule 10(i)</td>
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GOVERNMENT OF INDIA
DEPARTMENT OF ATOMIC ENERGY

Mumbai, the 25th August, 2004

G.S.R. 303.--- In exercise of the powers conferred by Section 30 read with Section 3
and clause (i) and sub-clauses (c) and (d) of clause (ii) of Sub-Section (1), Sub-Section
(4) of Section 14, and Sections 16, 17 and other relevant Sections of the Atomic
Energy Act (33 of 1962) and all other powers enabling it in this behalf, and in
supercession of Radiation Protection Rules 1971 except as respects things done or
omitted to be done before such supercession, the Central Government hereby makes
the following rules, namely:-

1. **Short title, extent and commencement:** - (1) These rules may be called the

   (2) These rules shall apply to practices adopted and interventions applied with
   respect to radiation sources.

   (3) They extend to the whole of India.

   (4) They shall come into force from the date of their final publication in the
   Official Gazette.

2. **Definitions.** - (1) In these rules, unless the context otherwise requires:-

   (a) "accident" means any unintended event, including operating error,
equipment failure or other mishap, the consequences or potential
consequences of which are not negligible from the radiation protection point
of view;

   (b) "Act" means the Atomic Energy Act, 1962 (33 of 1962);

   (c) "activation" means production of induced radioactivity by nuclear reactions;

   (d) "activity" means the average number of spontaneous nuclear
transformations taking place per unit time in a radioactive substance or
material;
(e) "adequate protection" means protection against radiation so provided that the regulatory constraints notified by the competent authority are not exceeded;

(f) "appropriate" means appropriate in the opinion of the competent authority to ensure adequate protection;

(g) "competent authority" means any officer or authority referred to in Section 27 of the Act;

(h) "contamination" means the presence of a radioactive substance in or on a material or in the human body or other place in excess of quantities specified in the relevant safety codes by the competent authority;

(i) "controlled area" means any area in which specific protection measures and safety provisions are or could be required for:

(a) controlling exposures or preventing the spread of contamination during normal working conditions; and

(b) preventing or limiting the extent of potential exposures;

(j) "conveyance" means:

(i) any vehicle for the purpose of transport by road;

(ii) any vessel, hold, or deck defined under the law being in force, for the purposes of transport by water; and

(iii) any aircraft for the purpose of transport by air;

(k) "decommissioning" means discontinuation of the use of radiation equipment or installation on a permanent basis, with or without dismantling the equipment, including removal or containment of radioactive materials;

(l) "dose" means absorbed dose, organ dose, equivalent dose, effective dose, or committed equivalent dose, or committed effective dose depending on the context;

(m) "employer" means any person who employs workers or imparts training using sources or who is self-employed as a worker, in a radiation installation;

(n) "exposure" means the act or condition of being exposed to radiation;

(o) "handle" means manufacture, possess, store, use, transfer by sale or otherwise, export, import, transport or dispose of;
(p) "intervention" means any action to reduce or avert exposure or likelihood of exposure to sources which are not part of controlled practice or which are out of control as a result of accident;

(q) "licence" means a licence issued under rule 3;

(r) "licensee" means a person to whom licence has been issued under these rules;

(s) "medical exposure" means exposure incurred by -

(i) patients as part of their own medical diagnosis or treatment;
(ii) persons, other than occupationally exposed, while knowingly and willingly helping in the support and comfort of patients; and
(iii) volunteers in biomedical research;

(t) "nuclear fuel cycle" means all operations associated with the production of nuclear energy, including mining, milling, processing of uranium or thorium; enrichment of uranium; manufacture of nuclear fuel; operation of reactors; reprocessing of nuclear fuel; decommissioning; radioactive waste management and any research or development activity related to any of the foregoing;

(u) "off-site emergency" means accident condition or emergency situation involving excessive release of radioactive materials/hazardous chemicals from the plant into public domain calling for an intervention;

(v) "person" shall include an individual or a company or association or body of individuals, whether incorporated or not; or Central Government or a State Government;

(w) "personnel monitoring" means determination or estimation of the dose received by an individual from external and/or internal radiation;

(x) "potential exposure" means exposure that is not expected to be delivered with certainty but which can result from an accident involving a source or due to an event or sequence of events of a probabilistic nature including equipment failure and operating errors;

(y) "practice" means any human activity that introduces additional sources or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, which may increase the exposure or likelihood of exposure of people, or the number of people exposed;
"quality assurance" means any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily, in compliance with safety standards specified by the competent authority, and includes quality control;

"quality control" means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of performance;

"radiation installation" means any location or facility, including a mobile facility, in which a radiation generating equipment or plant or radioactive material is present and which in the opinion of the competent authority requires radiation surveillance for ensuring adequate protection against radiation;

"radiation surveillance" means measures, including measurements and reviews performed, to ensure adequate protection;

"radiation work" means work involving exposure;

"radiation worker" means any person who is occupationally exposed to radiation;

"Radiological Safety Officer" means any person who is so designated by the employer with the approval of the competent authority;

"regulatory constraint" means restriction on radiation protection parameters notified by the competent authority;

"sealed source" means radioactive material that is -

(a) (i) permanently sealed in a capsule; or
(ii) in a solid form which is closely bounded and
(b) is designed to meet the safety standards prescribed by the competent authority;

"source" means a radioactive material or a radiation generating plant or equipment;

"supervised area" means any area not already designated as a controlled area but where occupational exposure conditions are kept under review even though specific protection measures and safety provisions are not normally needed;

"unsealed source" means any radioactive material that is not a sealed source; and
(2) "worker" means radiation worker.

(2) Words and expressions used in these rules and not defined but defined in the Act, shall have the meanings respectively assigned to them in the Act.

3. Licence:- (1) No person shall, without a licence -

(a) establish a radiation installation for siting, design, construction, commissioning and operation; and

(b) decommission a radiation installation.

(2) No person shall handle any radioactive material, or operate any radiation generating equipment except in accordance with the terms and conditions of a licence.

(3) A licence shall be issued for sources and practices associated with the operation of -

(i) nuclear fuel cycle facilities;
(ii) land based high intensity gamma irradiators other than gamma irradiation chambers;
(iii) particle accelerators used for research and industrial applications;
(iv) neutron generators;
(v) facilities engaged in the commercial production of radioactive material or radiation generating equipment;
(vi) telegamma and accelerators used in radiotherapy;
(vii) computed tomography (CT) unit;
(viii) interventional radiological x-ray unit;
(ix) industrial radiography; and
(x) such other source or practice as may be notified by the competent authority, from time to time.

Provided that for sources and practices associated with the operation of -

(i) brachytherapy;
(ii) deep x-ray units, superficial and contact therapy x-ray units;
(iii) gamma irradiation chambers;
(iv) nuclear medicine facilities;
(v) facilities engaged in the commercial production of nucleonic gauges and consumer products containing radioactive material; and
(vi) such other source or practice as may be notified by the competent authority, from time to time;

an authorisation shall be necessary.
Provided further that for sources and practices associated with the operation of -

(i) medical diagnostic x-ray equipment including therapy simulator;
(ii) analytical x-ray equipment used for research;
(iii) nucleonic gauges;
(iv) RIA laboratories;
(v) radioactive sources in tracer studies;
(vi) biomedical research using radioactive material; and
(vii) such other source or practice as may be notified by the competent authority, from time to time;

a registration shall be necessary.

Provided also that for -

(i) approval for siting, design, construction, commissioning and decommissioning of a radiation installation;
(ii) approval for sealed sources, radiation generating equipment and equipment containing radioactive sources, for the purposes of manufacture and supply;
(iii) approval for package design for transport of radioactive material;
(iv) approval for shipment approval for radioactive consignments; and
(v) such other source or practice as may be notified by the competent authority, from time to time;

consent shall be necessary.

(4) The licence shall not be transferable without the prior approval of the competent authority.

4. Fees for licence: The competent authority may prescribe by notification in the Official Gazette, appropriate fees payable for issuance of licence specified in these rules.

5. Exemption:- The use and disposal of a substance and materials which spontaneously emit radiation not exceeding the level of radiation prescribed by notification issued under clause (i) of Sub-Section (1) of Section 2 of the Act and the use of radiation generating equipment, devices or appliances emitting radiation not exceeding the limit determined by the Central Government under clause (g) of Section 3 of the Act, are exempted from the purview of rule 3.

6. Exclusion:- Exposures resulting from naturally occurring radionuclides present in the human body, cosmic radiation at the earth surface, unmodified concentrations of radionuclides in raw materials and from other sources and practices which may be prescribed as not amenable for control, are excluded from these rules.
7. **Conditions precedent to the issuance of a licence:**

(1) An application for licence shall be made by to the competent authority by an employer or a person duly authorized by him.

(2) No licence to handle radioactive material, or to operate radiation generating equipment, shall be issued to a person unless, in the opinion of the competent authority -

(a) the application for such licence is for purposes envisaged by the Act;

(b) documentation relevant to the licence and complete in all respects is submitted to the competent authority;

(c) in respect of approval for siting, design, construction, commissioning and decommissioning, of a radiation installation, the proposed equipment, facilities and handling procedures afford adequate protection during normal or intended operations;

(d) the applicant has demonstrated compliance with the provisions of the relevant safety codes and safety standards specified by the competent authority; and

(e) in respect of licence for operation of a radiation installation -

   (i) all the requirements relating to safety specified by the competent authority in the relevant safety codes and safety standards have been satisfied in the construction of the radiation installation;

   (ii) workers have appropriate training and instructions in radiation safety, in addition to the appropriate qualification and training required for performing their intended tasks;

   (iii) a Radiological Safety Officer is designated in accordance with rule 19;

   (iv) appropriate radiation monitors and dosimetry devices are available with the applicant for purposes of radiation surveillance;

   (f) the equipment, facilities and handling procedures afford adequate protection during normal operations, minimize occurrence of potential exposures and enable appropriate remedial actions to be taken in the event of an accident.

(3) No type approval of sealed sources, radiation generating equipment and equipment containing a radioactive source for the purpose of manufacture and supply or package design approval for transport of radioactive material or shipment approval for radioactive consignment or any other approval as notified under third proviso to rule 3, by the competent authority may be issued unless, in the opinion
of the competent authority, the applicant has demonstrated compliance with the relevant safety codes and safety standards specified by him.

8. **Issuance of licence**: The licence shall be issued within a period of one hundred and eighty days from the date of receipt of the application subject to the condition that all the requirements for issuance of the licence have been duly fulfilled.

9. **Period of validity of Licence**: Every licence issued under rule 3 shall, unless otherwise specified, be valid for a period of five years from the date of issue of such licence.

10. **Suspension, modification or withdrawal of a licence**: The competent authority may -

   (i) if in its opinion, the licensee has contravened any of the provisions of these rules; or

   (ii) considers it to be necessary in public interest pertaining to radiation safety;

   after giving a show cause notice to the licensee and also giving him an opportunity to make a representation within a period of thirty days from the date of receipt of the notice by him against the action proposed to be taken and on consideration of his representation,

   (a) suspend the operation of the licence for a specified period of time; or

   (b) revoke or modify the terms and conditions of the licence.

11. **Modification of radiation installation or change in working condition**: No modification to an existing radiation installation or no change in working conditions therein, affecting safety shall be done without the prior approval of the competent authority.

12. **Restrictions on use of sources**: (1) The licensee shall not handle any source:-

   (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) The licensee shall ensure that individuals other than those who may be specified in the licence do not handle the source.
13. **Restriction on certain practices**: (1) Practices such as deliberate addition of radioactive substances in foodstuffs, beverages, toys, personal ornaments, and cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being and sale, import or export of such products shall not be permitted.

(2) Activation of the aforesaid products shall not be permitted.

14. **Radiation symbol or Warning sign**: (1) The radiation symbol or warning sign shall be conspicuously and prominently displayed at all times -

(a) on externally visible surfaces of radiation equipment, and containers for storage of radioactive materials; packages for radioactive materials and vehicles carrying such packages;

(b) at the entrance to the room housing the radiation generating equipment; and

(c) at the entrance of controlled area and supervised area.

(2) The radiation symbol shall not be used for any purpose other than those mentioned in these rules.

(3) The specification of the radiation symbol or warning sign shall be as prescribed by the competent authority, by order for that purpose.

15. **Dose limits and other regulatory constraints**: The licensee shall ensure compliance with the dose limits and other regulatory constraints specified by the competent authority by order under these rules.

16. **Safety Standards and Safety Codes**: The competent authority may issue safety codes and safety standards, from time to time, prescribing the requirements for radiation installation, sealed sources, radiation generating equipment and equipment containing radioactive sources, and transport of radioactive material and the licensee shall ensure compliance with the same.

17. **Prohibition of employment of persons below certain age**: (1) No person under the age of 18 years shall be employed as a worker.

(2) No person under the age of 16 years shall be taken as trainee or employed as an apprentice for radiation work.

18. **Classified worker**: The employer shall designate as classified workers, those of his employees, who are likely to receive an effective dose in excess of three-tenths of the average annual dose limits notified by the competent authority and shall forthwith inform those employees that they have been so designated.
19. **Radiological Safety Officer:**- Every employer shall designate, with the written approval of the competent authority, a person having appropriate qualifications as Radiological Safety Officer.

20. **Responsibilities of the employer:**- (1) Every employer shall:

   (a) ensure that provisions of these rules are implemented by the licensee, Radiological Safety Officer and other worker(s),

   (b) provide facilities and equipment to the licensee, Radiological Safety Officer and other worker(s) to carry out their functions effectively in conformity with the regulatory constraints,

   (c) prior to employment of a worker, procure from his former employer, where applicable, the dose records and health surveillance reports,

   (d) upon termination of service of worker provide to his new employer on request his dose records and health surveillance reports,

   (e) furnish to each worker dose records and health surveillance reports of the worker in his employment annually, as and when requested by the worker and at the termination of his service,

   (f) inform the competent authority if the licensee or the Radiological Safety Officer or any worker leaves the employment, and

   (g) arrange for health surveillance of workers as specified under rule 25.

   (2) The employer shall be the custodian of radiation sources in his possession and shall ensure physical security of the sources at all times.

   (3) The employer shall inform the competent authority, within twenty four hours, of any accident involving a source or loss of source of which he is the custodian.

21. **Responsibilities of the licensee:**- (1) The responsibility for implementing the terms and conditions of the licence shall rest with the licensee.

   (2) The licensee shall comply with the surveillance procedures, safety codes and safety standards specified by the competent authority.

   (3) Every licensee shall establish written procedures and plans for controlling, monitoring and assessment of exposure for ensuring adequate protection of workers, members of the public and the environment and patients, wherever applicable.
(4) The licensee shall comply with the provision of rules for safe disposal of radioactive waste issued under the Act.

(5) Without prejudice to the generality of the above, the licensee shall

(a) not allow workers, other than those specified in sub-clause (ii) of clause (e) of sub-rule (2) of rule 7 and already dealt with under rule 17.

(b) maintain records of workers as specified under rule 24;

(c) arrange for preventive and remedial maintenance of radiation protection equipment, and monitoring instruments;

(d) in consultation with the Radiological Safety Officer, investigate any case of exposure in excess of regulatory constraints received by individual workers and maintain records of such investigations;

(e) inform competent authority promptly of the occurrence, investigation and follow-up actions in cases of exposure in excess of regulatory constraints, including steps to prevent recurrence of such incidents;

(f) carry out physical verification of radioactive material periodically and maintain inventory;

(g) inform appropriate law enforcement agency in the locality of any loss of source;

(h) inform the employer and the competent authority of any loss of source;

(i) investigate and inform the competent authority of any accident involving source and maintain record of investigations;

(j) verify the performance of radiation monitoring systems, safety interlocks, protective devices and any other safety systems in the radiation installation;

(k) in consultation with Radiological Safety Officer, prepare emergency plans, as specified in rule 33, for responding to accident to mitigate their consequences and ensure emergency preparedness measures;

(l) conduct or arrange for quality assurance tests of structures, systems, components and sources and related equipment;

(m) advise the employer about the modifications in working condition of a pregnant worker;
(n) inform the competent authority if the Radiological Safety Officer or a worker leaves the employment; and

(o) inform the competent authority when he leaves the employment.

(6) The licensee shall ensure that the workers are familiarised with contents of the relevant surveillance procedures, safety standards, safety codes, safety guides and safety manuals issued by the competent authority and emergency response plans.

22. **Responsibilities of the Radiological Safety Officer:**

(1) The Radiological Safety Officer shall be responsible for advising and assisting the employer and licensee on safety aspects aimed at ensuring that the provisions of these rules are complied with.

(2) The Radiological Safety Officer shall:

(a) carry out routine measurements and analysis on radiation and radioactivity levels in the controlled area, supervised area of the radiation installation and maintain records of the results thereof;

(b) investigate any situation that could lead to potential exposures;

(c) advise the employer regarding -

   (i) the necessary steps aimed at ensuring that the regulatory constraints and the terms and conditions of the licence are adhered to;

   (ii) the safe storage and movement of radioactive material within the radiation installation;

   (iii) initiation of suitable remedial measures in respect of any situation that could lead to potential exposures; and

   (iv) routine measurements and analysis on radiation and radioactivity levels in the off-site environment of the radiation installation and maintenance of the results thereof;

(d) ensure that -

   (i) reports on all hazardous situations along with details of any immediate remedial actions taken are made available to the employer and licensee for reporting to the competent authority and a copy endorsed to the competent authority;
(ii) quality assurance tests of structures, systems, components and sources, as applicable are conducted; and

(iii) monitoring instruments are calibrated periodically.

(e) assist the employer in -

(i) instructing the workers on hazards of radiation and on suitable safety measures and work practices aimed at optimising exposures to radiation sources; and

(ii) the safe disposal of radioactive wastes; and

(iii) developing suitable emergency response plans to deal with accidents and maintaining emergency preparedness;

(f) advise the licensee on -

(i) the modifications in working condition of a pregnant worker; and

(ii) the safety and security of radioactive sources;

(g) furnish to the licensee and the competent authority the periodic reports on safety status of the radiation installation; and

(h) inform the competent authority when he leaves the employment.

23. **Responsibilities of worker:**-(1) Every worker shall observe the safety requirements and follow safety procedures and instructions and shall refrain from any wilful act that could be detrimental to self, co-workers, the radiation installation and public.

(2) The worker shall:-

(a) provide to the employer information about his previous occupations including radiation work, if any;

(b) make proper use of such protective equipment, radiation monitors and Personnel monitoring devices as provided; and

(c) inform the licensee and the Radiological Safety Officer, of any accident or potentially hazardous situation that may come to his notice;

(3) A female worker shall, on becoming aware that she is pregnant, notify the employer, licensee and Radiological Safety Officer in order that her working conditions may be modified, if necessary.
24. **Records of workers:** (1) Every licensee shall maintain complete and up-to-date records of -

   (a) personnel monitoring under Clause (b) of sub-rule (2) of rule 27, in the format as specified by order by the competent authority; and

   (b) the health surveillance specified in rule 25.

(2) Such records shall be preserved during the working life of each worker, and afterwards until the worker attains or would have attained the age of Seventy five years, or not less than thirty years after the termination of the work involving occupational exposure whichever is later.

(3) A worker shall have access to his personnel monitoring and the health surveillance records.

25. **Health surveillance of workers:** (1) Every employer shall provide the services of a physician with appropriate qualifications to undertake occupational health surveillance of classified workers.

(2) Every worker, initially on employment, and classified worker, thereafter at least once in three years as long as the individual is employed, shall be subjected to the following -

   (a) general medical examination as specified by order by the competent authority; and

   (b) health surveillance to decide on the fitness of each worker for the intended task;

(3) The health surveillance shall include -

   (a) special tests or medical examinations as specified by order by the competent authority, for workers who have received dose in excess of regulatory constraints; and

   (b) counselling of pregnant workers.

26. **Medical exposures:** The licensee carrying out diagnostic or therapeutic work using radiation generating equipment, sealed or unsealed sources, shall for optimizing the medical exposure ensure that -

   (a) performance of the equipment is verified periodically by appropriate quality assurance tests;

   (b) records are maintained for a period specified by the competent authority of -
(i) radiation doses received by therapy patients;

(ii) activity administered to patients for diagnostic and therapeutic purposes; and

(iii) other relevant parameters;

(c) the exposure of humans for bio-medical research is carried out only on healthy volunteers with their prior consent in writing. The methodology, the number of volunteers and the radiation dose they are subjected to shall be reviewed by the ethical review committee constituted by the employer; and

(d) any accidental medical exposure is investigated and a written report is submitted to the competent authority.

27. **Radiation surveillance requirements**: (1) The competent authority may by order specify appropriate radiation surveillance requirements and procedures and the employer and the licensee shall comply with them.

(2) Without prejudice to the generality of the foregoing provisions, such radiation surveillance requirements and procedures may provide that -

(a) the siting, design, construction, commissioning, operation, servicing and maintenance and decommissioning of facilities involving the use of radiation, and disposal of radioactive material shall be done in accordance with the specifications laid down by the competent authority in the relevant safety codes and safety standards;

(b) the workers shall be subjected to personnel monitoring and health surveillance and appropriate records shall be maintained;

(c) transport of radioactive material in public domain shall be in accordance with the procedures laid down by the competent authority and in accordance with the other regulations pertaining to transport by different modes; and

(d) appropriate quality assurance requirements in the above.

28. **Directives in the cases of exposures in excess of regulatory constraints**: (1) When, in the opinion of the competent authority, any worker has exceeded the dose constraints, the competent authority may, without prejudice to other course of action available, issue appropriate directives for controlling further exposure and the employer shall comply with the directives.

(2) If a worker discontinues radiation work under the directives of the competent authority issued under this rule, the employer shall assign alternative work not
involving exposure to radiation, until the competent authority is satisfied about the fitness of the worker to resume radiation work.

(3) The employer shall comply with restrictions, if any, that the competent authority may impose in this regard.

29. **Power to appoint or recognize persons or agencies**:- The competent authority may, from time to time, appoint or recognize persons or agencies having the qualifications and expertise, prescribed in the relevant safety code, for the purpose of performing any of the functions entrusted to them by the authority and for ensuring compliance with radiological surveillance.

30. **Inspection of premises, radiation installations and conveyances**:- (1) Any person duly authorised under sub-Section (4) of Section 17 of the Act may, for the purposes of enforcement of these rules, inspect any premises, or radiation installation, or conveyance.

(2) The date and time of inspection may or may not be informed to the employer or the licensee prior to the inspection.

(3) The employer and the licensee shall extend all assistance to enable the inspection to be carried out effectively and unhindered.

(4) The findings of the inspection shall be forwarded to the licensee for necessary corrective actions.

(5) Inspection may be carried out at all licencing stages, namely, siting, construction, commissioning, operation and decommissioning.

(6) The person authorised to conduct inspection may -

(a) Inspect, from safety point of view, to ensure that the licensee has fulfilled the radiological safety requirements for carrying out the practices at the radiation installation as per the stipulations laid down in the licence. This shall include -

(i) checking, whether the safety related structures, systems, components and devices are of approved quality based, on the relevant safety codes and safety standards specified by the competent authority and that they are functioning as per the design intent, (checking that respective operating personnel are competent to operate the facility;

(ii) that the facilities are operating as per the approved technical specification; and
(iii) conducting all such examinations (including verification of relevant records) as may be considered necessary;

(b) make such tests and measurements as may be necessary for the purpose of assessing radiation safety;

(c) investigate unusual incidents or accidents, if any, that had occurred at the radiation installation and arrive at the reasons for the same and recommend corrective measures;

(d) review and verify whether the corrective actions have been implemented; and

(e) inspect radioactive consignments in any conveyance carrying radioactive material and inspect any package containing radioactive material.

31. **Power to investigate, seal or seize radiation installation or radioactive material and to give direction to the employer:**

(1) Any person duly authorised under Section 17 of the Act, may, after inspection, carry out investigation for the purposes of determining contravention of any of the provisions of these rules;

(2) The investigation may be carried out against a complaint or on suspicion or after an unusual incident or accident;

(3) The person authorised to investigate may -

(a) seal any radiation installation or any conveyance carrying radioactive materials or seize any radioactive material or contaminated equipment; and

(b) indicate in writing to the employer any recommendation aimed at ensuring adequate protection and the licensee shall comply with the same.

32. **Directives in case of accidents:**

(1) In the event of an accident involving the source or release of radioactive material, the competent authority may -

(a) Intervene and issue such directions as deemed fit and proper under the circumstances in the interest of radiation safety and the employer shall act as per the directions of the competent authority and shall make every effort to mitigate the consequences of the accident, or

(b) The competent authority may assign experts to give advice or render assistance in mitigating the consequences of the accident and the expenses incurred, if any, shall be reimbursed by the employer.
(2) In the interest of safety of the radiation installation, workers, public and the environment, the competent authority may issue such directions as it may deem fit for ensuring safety including the immediate shutting down of the radiation installation and the employer shall comply with the directions.

33. **Emergency preparedness:** (1) The licensee shall prepare emergency response plans as specified by the competent authority in the relevant safety codes and maintain emergency preparedness.

(2) The licensee shall submit the response plans for plant emergencies and site emergencies to the competent authority for approval.

(3) The licensee shall submit the response plans for off-site emergencies prepared by the appropriate authorities to the competent authority for review.

(4) In respect of radiation installations governed by clause (a) of sub-rule (3) of rule 3 and clause (b) of sub-rule (3) of rule 3, emergency response plans shall be submitted to the competent authority prior to the commissioning of the installations.

(5) Any modification to the emergency plan shall require prior approval of or review by the competent authority.

34. **Decommissioning of radiation installation:** (1) When a radiation installation or radiation generating equipment ceases to be in use, the employer shall ensure its decommissioning.

(2) No employer shall decommission a radiation installation without the prior approval of the competent authority.

(3) The decommissioning plan shall take due cognizance of disposal of radioactive wastes, recycling of materials, and reuse of equipment and premises.

(4) The licensee shall comply with such directive as may be issued by the competent authority to ensure adequate protection of the persons in and around the decommissioned installation.

35. **Offences and penalties:** Any person who contravenes the provisions of these rules or any of the terms and conditions of licence issued hereunder, shall be punishable as provided for under the Act.

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V.P. RAJA. Jt. Secy.