CURRENT RADIOACTIVE WASTE MANAGEMENT CHALLENGES IN NUCLEAR MEDICINE

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The paper analyzes solid and liquid radioactive waste management methods implemented within radionuclide diagnostics and therapeutical units of Russian healthcare organizations. It evaluates the degree of compliance between the established RW management practice and relevant requirements set forth in Rospotrebnadzor's regulations and ICRP and IAEA recommendations. It reveals a number of unscientifically based provisions that correspond neither to international recommendations nor the long-term national and international practice in nuclear medicine. It specifies a number of proposals on introducing relevant amendments to the developed regulations that are to be enforced following the "regulatory guillotine".

Keywords: *radiation safety, nuclear medicine, radioactive waste, regulations, "regulatory guillotine".*

Introduction

Sources of ionizing radiation are widely used in modern medicine. Scientific research and clinical practice of their application are combined within such a high-tech discipline as medical radiology, which, in turn, involves radiation diagnostics, radiation therapy and nuclear medicine. In radiation diagnostics, both generating sources of ionizing radiation (X-ray diagnostic devices of various types) and devices of non-ionizing radiation (ultrasound, magnetic resonance imaging, laser medicine) are used. In radiation therapy, gamma-therapy devices with sealed radionuclide sources have been massively replaced by generating sources of ionizing radiation (linear electron accelerators, proton and ion accelerators). At the same time, both in radiation diagnostics and radiation therapy, no technologies are in place that result in radioactive waste (RW) generation.

A reverse trend is observed in nuclear medicine with all relevant technologies being based on the use of open radionuclide sources. Its main branch corresponds to radionuclide diagnostics (RND) *in vivo*: it is used to detect the presence, nature, severity and prevalence of a pathological process in the patient's body, as well as a relapse of a disease and to evaluate the effectiveness of a treatment based on the visualized spatial and temporal distribution of a diagnostic radiopharmaceutical (RP) introduced into the patient's body using planar scintigraphy, single-photon emission computed tomography (SPECT) and positron emission tomography (PET).

Another branch of nuclear medicine is RND *in vitro* providing the identification of various hormones, enzymes, tumor markers and other biological compounds in patients' venous blood samples by competitive binding of the sought stable substances

and similar radioactive ones with specific systems in these samples.

The third branch of nuclear medicine, namely, the radionuclide therapy (RNT) is advancing most rapidly. It is a radical or palliative treatment of oncological, endocrinological and other diseases when some therapeutic radiopharmaceuticals, the activity of which is much higher than in radiodiagnostic *in vivo* studies, are introduced into patient's body. Since patients undergoing RNT with some β-γ-emitting radiopharmaceuticals pose certain radiation hazard to staff and the public, they are hospitalized in a secure way and held for several days in "active" wards of RNT units.

Under routine operation and a fortiori in case of radiation accidents, all three branches of nuclear medicine provide for generation, collection, storage and disposal of solid (SRW) and liquid (LRW) radioactive waste (RW).

RW management in nuclear medicine subdivisions is currently regulated by a number of regulatory documents. First of all, these include NRB-99/2009 [1] and OSPORB-99/2010 as amended in 2013 [2] having the highest legal status, as well as SPORO-2002 providing general RW management rules [3]. Hygienic radiation safety requirements, including those concerning SRW and LRW management in nuclear medicine departments are specified in the following documents with a lower legal status:

- RND *in vivo* in general — MU 2.6.1.1892-04 [4];
- positron emission tomography (PET) considered a most important RND technology *in vivo* — SanPiN 2.6.1.3288-15 [5];
- RND *in vitro* — MU 2.6.1.2808-10 [6];
- RNT — SanPiN 2.6.1.2368-08 [7].

To implement the decision of the Government of the Russian Federation on the "regulatory guillotine", all of the above documents [1]—[7] were processed and combined into general sanitary and epidemiological requirements in the field of radiation safety, and this document was posted on Internet for discussion [8]. At the same time, the list of abolished regulations involved only NRB-99/2009 [1], OSPORB-99/2010 as amended in 2013 [2] and SPORO-2002 [3], as well as SanPiNs [5] and [7], while guidelines [4] and [6] were not indicated in this list. However, in October 2021, this project was significantly reduced and submitted for review only to relevant departments in the form of a letter from Rospotrebnadzor [9], which is not yet available on the Internet. Since drafts [8], [9] have not yet been officially approved, further consideration is expected to affect only the currently valid regulations [1]—[7].

As regards international RW management recommendations, including those effective in nuclear medicine, the ICRP Publications (International Commission on Radiation Protection) [10], [11] seem to be of a particular importance. Among over 30 IAEA Publications being directly or indirectly related to the problem of RW management in general and in medicine in particular, particular consideration should be given to a few publications [12]—[14] and Technical Reports [15]—[17].

This study evaluates national regulations on RW management in nuclear medicine and compares existing requirements with the international recommendations and the established long-term clinical practice in national and international nuclear medicine. It also provides some proposals on enhancing the regulations under the abovementioned "regulatory guillotine" and after its completion.

Solid radioactive waste management

Without dwelling on the methods for collection, storage and disposal of numerous SRW, the requirements for which are well developed and regulated in detail by documents [1]—[7], it should be noted that they are considered scientifically sound and convenient for clinical users. It can only be noted that the greatest SRW management challenge is mainly associated with their relatively large volume, primarily in RNT departments, where a large storage area is required to provide their decay storage especially given the intensive flow of patients undergoing RNT treatment in a hospitalization mode.

In terms of proposals that can be made on the enhancement of SRW management in nuclear medicine subdivisions, it should be noted that, in contrast to the current documents [2], [4], [7], drafts [8], [9] provide no section at all on RW management with only one reference indicated to the Decree of the Government of the Russian Federation No. 1069 of October 19, 2012, which specifies the criteria that can be used to categorize waste as RW according to a number of radionuclides [18]. At the same time, their list seems incomplete: in particular, it does not mention the radionuclides available in SRW of RND *in vivo* and PET units (^{44}Sc, ^{67}Ga, ^{68}Ga, ^{89}Zr, ^{124}I), as well as RNT units (^{67}Cu, ^{169}Yb, ^{117m}Sn, ^{149}Tb, ^{213}Bi, ^{225}Ac). This approach may significantly complicate the management of the above SRW, especially in RNT subdivisions, where the use of radiopharmaceuticals with α-emitting radionuclides ^{149}Tb, ^{213}Bi, ^{225}Ac has been already started.

Liquid radioactive waste management

Radionuclide diagnostics *in vivo*. First, it should be noted that from a formal point of view, no LRW is generated during the operation of *in vivo*

RND subdivisions, therefore they are not even mentioned in MU 2.6.1.1892-04 [4]. The only exception are the emergencies associated with the spillage of radioactive solutions, as well as periodic quality control of gamma cameras with liquid phantoms. In these cases, the applied radioactive solution collected in a container is placed in a radioactive waste storage facility for decay storage followed by its discharge into a domestic sewerage system.

Nevertheless, LRW can be generated from routine operation of RND units *in vivo*, since every patient with radiopharmaceuticals introduced into his body becomes a source on his own. First of all, some 90—95 % of all radiodiagnostic studies *in vivo* are carried out on an outpatient basis, i. e., patients are not staying in a hospital. Another feature of these studies is the formation of a relatively large volume of low-level LRW in the form of radioactive urine from the treated patients. At the same time, the patient excretes approximately 30—40 % of the introduced radiopharmaceutical activity while staying at the RND unit, since before the measurements take place, the patient is always sent to urinate in a toilet intended for patients. This avoids the overlaying of the bladder's scintigraphic image with its radioactive content by the images of other anatomical body structures located in the same area of human body. However, most of the introduced activity is taken home by the patient inside his body, where he gradually discharges the radioactive urine into the municipal sewerage system.

This situation causes contradictions between OSPORB-99/2010 as amended in 2013 [2] and the main regulatory document on RND *in vivo*, namely MU 2.6.1.1892-04 [4]. The fact is that the specific radioactivity of urine emitted in the toilet for patients usually amounts to $(2—5)\cdot10^5$ kBq/kg, and the total volume of such LRW in a RND unit even of a medium capacity (20—30 patients per day) exceeds 300—400 liters per day (mainly LRW with ^{99m}Tc and ^{123}I, somewhat less with ^{18}F and ^{68}Ga, less often with ^{111}In, ^{67}Ga, ^{75}Se, ^{131}I, ^{201}Tl). In accordance with paragraph 3.12.10 [2], such LRW is categorized as intermediate-level waste with some specific numerical criteria for such waste categorization as LRW established for a number of them in [18]. Therefore, it is formally required to organize waste collection via a special sewerage system providing their subsequent decay storage.

However, in Russian RND units, no one does this for the following two reasons: 1) the largest share of the introduced activity is released to the city household sewerage not by medical institutions, but via a public network of the same sewerage system from outpatients staying at home after radionuclide treatment; 2) activity in the composition of wastewater from both sources gets heavily diluted on its way through the effluents and collectors to the city aeration station, especially in cities with a population of over one million people. Both reasons demonstrate that collection of radioactive urine both at patient homes and in the clinic where the patients are undergoing the radionuclide treatments and studies makes no sense at all.

Yet another circumstance contributes to the status quo providing no need for collection of radioactive urine both in clinics and at home: almost all diagnostic radiopharmaceuticals are labeled with radionuclides that decay emitting γ-radiation only and no β-particles are emitted in the process (with the exception of positron-emitting ^{18}F, ^{68}Ga, ^{89}Zr, ^{124}I). These include primarily ^{99m}Tc (up to 80 % of all radionuclide studies), as well as ^{123}I, ^{67}Ga, ^{111}In, ^{113m}In, ^{199}Tl, ^{201}Tl, so radioactive urine with such radiopharmaceuticals does not automatically fall under the action of Table. 3.12.1 from [2], in which "pure" γ-emitting radionuclides are simply ignored. In other words, according to [2], such γ-radioactive urine formally cannot be considered liquid RW.

The above circumstances prompted the inclusion of p. 3.14.5 into the current methodological guidelines MU 2.6.1.1892-04 [4], according to which presence of special sewage in RND units *in vivo* is not required, and all LRW can be discharged directly into the household sewerage. The same is indicated in clause 3.4.10 of SanPiN 2.6.1.3288-15 [5] for PET centers.

Apparently, the combination of all reasons mentioned above explains why the documents [2], [4] do not consider the case of LRW in domestic radionuclide diagnostics *in vivo*. This circumstance appears to be quite beneficial for existing RND units, as it does not force them to incur unjustified economic costs for the establishment and operation of special sewerage systems that would not actually increase the radiation safety level for patients, personnel, the public and the environment.

Thus, specific RW management instructions provided in regulatory documents [4], [5] formally contradict OSPORB-99/2010 [2]. Therefore, during the next review of OSPORB provisions the "regulatory guillotine" should be followed by the legalization of the mentioned case so that the established long-term practice of LRW management in RND units *in vivo* and PET centers could be accounted for, since it is believed basically impossible to arrange centralized collection and decay storage of radioactive urine from patients in these units, and even more so outside, i. e., at home.

It seems also reasonable to remove all items related to PET from the guidelines [4], since a more detailed document, namely, SanPiN 2.6.1.3288-15

is in place to discusses this technology [5]. Requirements provided in [4], namely, those concerning the radiation monitoring with the volumetric activity of radioactive aerosols being measured in the air of working premises and the specific activity of drain waters discharged into the domestic sewer are also considered redundant, since, in accordance with p. 3.14.5 of this document [4], these waters are already recognized as meeting the radiation safety standards. Also redundant in [5] are the requirements for the collection and short-term storage (1 day) of process solutions for disinfection and decontamination of "hot" boxes in PET centers, which can be disposed of into the domestic sewer immediately after their generation with no decay storage required.

Radionuclide diagnostics *in vitro*. As in *in vivo* RND, *in vitro* RND (radioimmunoassay, RIA) also results in LRW generation: unbound radioactivity drained from tubes, the fraction of which usually accounts for 20—40 % of the ^{125}I activity poured into each tube. Before the guidelines [6] were enacted, RIA operations were mainly arranged in keeping with the provisions of Appendix 4 to NRB-99/2009 [1] providing for a minimum significant activity MSA = 1 MBq indicated for ^{125}I taking into account the fact that the activity level at the workplace with RIA actually does not exceed 200—500 kBq ^{125}I. According to [6], LRW should be discharged into a conventional sewer system provided preliminary dilution (at least with 1 liter of water per 20 test tubes), while these actions are prohibited by other regulations [2], [3]. And although paragraph 7.5 does not refer to diluting water, but rather to a disinfectant liquid, this does not change the essence of the matter.

However, in practice, almost all domestic subdivisions of RND *in vitro* are currently discharging LRW directly into the sewer given its dilution by several orders of magnitude on the way to the aeration station. This approach appears quite consistent with elementary common sense, especially in cases when *in vitro* and *in vivo* studies are performed in the same nuclear medicine division, where radioactive urine from patients (hundreds of MBq) is mixed in the same sewerage system with LRW from *in vitro* studies (only tens of kBq).

Further, RIA studies most commonly involve some kits, in which the radioisotope of iodine ^{125}I is used as a radioactive label. Similarly, to labels in RND *in vivo*, ^{125}I is not considered a β-emitting radionuclide, since it decays by capturing an orbital electron after which only low-energy characteristic and γ-radiation are in place, i. e., LRW with ^{125}I do not fall within the scope of table 3.12.1 in [2] and formally such waste should not be categorized as LRW. Thus, in RND *in vitro* another contradiction is in place between the regulatory documents [1], [6] on the one hand and [2], [3] on the other hand, it should be taken into account during further revision of OSPORB provisions.

If, however, waste with ^{125}I is considered liquid RW, then document [6] formally contradicts the requirements of both [2] and [19], since both versions of OSPORB prohibit LRW dilution to reduce its activity (see paragraph 3.12 .17). In addition, reference to Appendix 3 of the document [19] was deleted from [2], while the guidelines [6] are based precisely on this reference.

Considering the general state of uncertainty associated with [6] and the lower legal status of guidelines [6] compared to [2], one can conclude that OSPORB-99/2010, as amended in 2013, has a negative impact on the legal setup when it comes to RIA procedures implemented according to the established long-term practice. Unfortunately, draft regulations [8], [9] ignored this controversial situation, since they did not mention the existence of RND *in vitro* at all.

Radionuclide therapy. Radionuclides ^{89}Sr, ^{153}Sm and ^{188}Re have long been used in Russian RNT for the palliative treatment of bone metastases. Quite recently, for the same purpose, the use of α-emitting radiopharmaceuticals based on ^{223}Ra was started. At the same time, treatment with ^{89}Sr is performed on an outpatient basis since it is a "pure" β-emitting radionuclide, while the treatment with β-γ-emitting radionuclides ^{153}Sm, ^{188}Re and ^{223}Ra is implemented in a day patient mode. Application of these radionuclides for RNT results in only one LRW type, namely, radioactive urine from patients. At the same time, it is characterized by significantly higher specific radioactivity levels than those indicated in Appendix 5 to [2]. Nevertheless, there are no restrictions and practical recommendations on the collection of radioactive urine from patients undergoing outpatient RNT treatment involving these radionuclides, although in accordance with [2], this case formally requires its collection, at-home storage and subsequent removal to LRW treatment station in the RNT center.

It seems quite obvious that the listed procedures cannot be implemented under real life conditions. In addition, for LRW with α-emitting radionuclides, including α-β-γ-emitting radionuclide ^{223}Ra, p. 5.15 of SPORO-2002 [3] requires that it is collected and stored separately from β-emitting LRW. Obviously, the listed procedures are beyond elementary common sense and practically cannot be implemented in real life.

However, most of RNT procedures implemented in Russia and abroad involve ^{131}I radionuclide

applied to treat patients with hyperthyroidism (300—800 MBq) and differentiated thyroid cancer (3—7 GBq). Usually, following oral intake of ^{131}I, patients are hospitalized in a restricted regimen to "active" wards where they have to stay for 2—4 days depending on the activity introduced and the type of the disease.

In accordance with SanPiN 2.6.1.2368-08 [7], if no radiation accidents occur and the operations in the RNT department involving open radionuclide sources are performed according to the standards, intermediate-level LRW includes:

- unused residues of radioactive solutions from vials, beakers and radiopharmaceutical packages;
- toilet flushes in outpatient toilets;
- drain water from toilet bowls, sinks and showers (if any) in the bathrooms of "active" wards;
- drain and waste water from sanitary checkpoints for patients;
- drain and waste water from packing, generating and washing units.

The generated LRW from the "active" chambers is discharged into a special sewerage system in accordance with SanPiN [7]. Typically, such a system contains several storage tanks, where LRW with ^{131}I is stored to reduce its specific radioactivity to a level specified in national regulations.

Prior to the enactment of OSPORB-99/2010 provisions as amended in 2013 [2], the capacity of a special cleaning station in each RNT subdivision was calculated based on the standard level of 100 kBq/kg specified in NRB-99/2009 [1] and in the previous version of OSPORB-99/2010 of 2010 [19]. However, under the revised OSPORB-99/2010 version of 2013 [2], the standard for LRW with ^{131}I unexpectedly became much stricter — it was increased by 161 times to 0.62 kBq/kg, which has no clear scientific justification from the radiation-hygienic and radioecological points of view. This tightening was not discussed by general scientific community. The article [20] describing the background of this decision indicates that Rospotrebnadzor and FMBA of Russia insisted on maintaining in [2] the criteria for waste categorization as radioactive waste established in [19], but the Ministry of Natural Resources of Russia, State Corporation Rosatom, Rostekhnadzor and Nuclear Safety Institute of RAS requested that the criteria for liquid waste categorization as radioactive were kept as established in the previous version of OSPORB-99 [21], i. e. to 10 intervention levels for drinking water. Unfortunately, the conservative outlook has won and therefore the above regulations were enforced [2], [3]. However, as already mentioned above, Russian literature provides no rational for the decision on tightening the LRW standards both generally in the field of radioecology and in nuclear medicine in particular, and therefore they should be considered scientifically unfounded. A paper [20] from the P. V. Ramzaev Research Institute of Radiation Hygiene (St. Petersburg) run by Rospotrebnadzor also notes that "the introduction of a voluntaristic definition for liquid radioactive waste should be recognized as unjustified", which may be unconditionally admitted.

For operating RNT subdivisions this necessitates the upgrading of special treatment stations which should be additionally fitted with new tanks, in which the waste will be kept for a much longer time (up to 4 months) than before. If such upgrading is considered impossible (lack of funding, limited working area of the station), it would be necessary to reduce the inflow of treated patients. In addition, increased decay storage time may result in an unjustified increase in the occupational exposure of personnel engaged in the operation of the LRW special treatment unit due to a longer time of personnel contact with the special sewerage system.

Thus, the decision on tightening the LRW standards in [2], [3] causes completely unjustified economic costs and (or) a decreased throughput of RNT departments with no increase in the radiation safety of the population and the environment, but provided its inevitable decrease for the personnel.

As for the proposed improvements that can be introduced to RNT regulations, the new version of SanPiN [7] should be added with a provision on the possibility of RNT studies in the premises of RND units *in vivo*, if the radiopharmaceutical used is intended for outpatient treatment. Due to the very low specific activity and large volume, the discharge of such water from the washbasins and showers in the "active" wards should be allowed not to a special sewerage system, but directly into domestic sewerage systems.

It is appropriate to point out that in all premises of radionuclide support units and "active" wards, class II operations involving open radionuclide sources are allowed to be performed. The use of home clothes should be allowed instead of expensive one-time clothes for patients during hospitalization, provided that these are categorized as SRW upon patient's discharge from the hospital. Redundant in [7] seem the requirements concerning the decay storage of radioactive food waste from patients and regular radiometric (except for dosimetric) monitoring of personnel.

OSPORB-99/2010 as amended in 2013, other regulations and international recommendations

Unlike previous OSPORB versions, [2] does not indicate other regulations subject to correction or even cancellation due to the new LRW requirements.

The only exception were the Sanitary Rules for Radioactive Waste Management (SPORO-2002), which were amended in accordance with [2] (amendment No. 2) [3].

The above analysis has already revealed certain contradictions between the requirements [2] and the currently valid regulatory provisions [4]—[7], but what is even more surprising these provisions do not correspond to NRB-99/2009 [1], i. e., to the document with the highest legal status. In particular, for ^{131}I, NRB-99/2009 specifies the minimum significant specific activity (MSSA) of 100 kBq/kg. Undeniably, the MSSA in NRB and in LRW criteria specified in [2], [18] have fundamentally different meanings and suggest different areas of practical application. However, both documents provide no clear recommendations on the practical application of these standards in a given situation. The authors of OSPORB-99/2010 version as amended in 2013 did nothing to eliminate this contradiction.

ICRP Publications [10] and IAEA Reports [12]—[15] present general RW management principles and recommendations, including SRW and LRW in medicine, which seem to be fairly harmonized with the national regulatory framework [1], [4]—[7].

As for the compliance of the requirements stated in [2], [3] with the international recommendations, there are some contradictions here as well. In particular, in IAEA Publication 1202 [12] for ^{131}I, the standard providing for exemption or clearance from radiation control, specifies a specific activity level of 10 kBq/kg, in contrast to the standard of 0.62 kBq/kg provided in the current version of OSPORB-99/2010. In later IAEA Publication 1578 [14], the same standard has been already decreased to 100 kBq/kg, thereby, formally meeting the standard for MSSA provided in NRB-99/2009 [1]. Moreover, IAEA Publication 1207 [13] states that the waste generated during *in vitro* RND should not be considered radioactive at all, collection of radioactive urine in *in vivo* RND units is impractical and RNT LRW may be diluted before being discharged into domestic sewerage systems.

ICRP Publication 94 [11] deserves particular interest since it indicates that the construction of stations for the special LRW treatment in RNT divisions is impractical as it requires enormous construction and operation costs (up to 80 % of the total cost of the radiological building) and provides increased radiation safety neither for personnel and the population, nor for the environment and does not comply with the widely recognized ALARA principle. Dilution of discharged LRW by several orders of magnitude in domestic sewerage system provides effective occupational exposure doses for workers at urban aeration stations of only 40—240 μSv/year, and most of this dose is associated with LRW containing not ^{131}I from RNT, but ^{99m}Tc in the radioactive urine of outpatients undergoing RND *in vivo* treatment. The same idea was also confirmed in IAEA Technical Reports 1183 and 1608 [16], [17] emphasizing that both the dilution of LRW from RNT departments and the direct discharge of the same LRW into the domestic sewerage system without its prior dilution is feasible if developed urban infrastructure for wastewater disposal is available.

Therefore, ICRP and IAEA not only do not see the need for any tightening of the recommendations on the ^{131}I-containing waste discharges into the common sewerage, but in general they argue that such discharges are reasonable and admissible with no need for a decay storage of medical LRW. In accordance with basic ICRP and IAEA principles, these recommendations are not rigidly imposed, and the decision-making on the decay storage of LRW in RNT units is proposed to be implemented in keeping with the national legal framework in the field of radiation safety. However, at present, in North America, Western Europe, Australia and Japan, the decommissioning of LRW special treatment plants is gradually taking place in nuclear medicine departments, especially in large cities, due to their ineffective application for radiation safety purposes and the economic infeasibility of their further operation.

Conclusions

1. Essential contradictions in the provisions of current OSPORB-99/2010 as amended in 2013 and a number of national regulations and international recommendations demonstrate poor professional consideration of the requirements present in this document and a completely ridiculous gap between the old and the new standards (more than 160 times for ^{131}I and up to 200 times for other radionuclides), which suggests the opportunistic rather than scientific nature of the adopted amendments.

2. Negative impact of OSPORB-99/2010 as amended in 2013 on the operation of radionuclide therapy units, which are forced to resort to unjustified economic costs providing no increase in the radiation safety of patients, the public and the environment, while actually reducing this level for the personnel of these units, appears to be particularly pronounced.

3. This case study shows that the unreasonable standards set forth for LRW in nuclear medicine should be abolished and a separate regulation (preferably SanPiN) focused on the management of SRW and LRW in the departments of radionuclide

diagnostics *in vivo*, *in vitro* and radionuclide therapy should be developed.

4. Upon completing the "regulatory guillotine", these contradictions should be eased in the provisions of general sanitary and epidemiological requirements in the field of radiation safety currently being under development and relevant hygienic requirements present in this document should be harmonized primarily with NRB-99/2009 and international recommendations and comply with the established national and international long-term practice applied in nuclear medicine.

5. In the long term, it is advisable to raise a question on the potential recognition of all liquid waste in nuclear medicine units as non-radioactive waste providing its exemption from radiation control, as well as gradual decommissioning of LRW special treatment plants currently operating in domestic radionuclide therapy units in accordance with the international recommendations.

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