POLICY ISSUE
(Information)

December 27, 2006 SECY-06-0248

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: RESULTS OF STAFF ACTIONS TO IDENTIFY PROBLEMS IN AUTHORIZING MEDICAL PHYSICISTS UNDER 10 CFR PART 35 IN RESPONSE TO STAFF REQUIREMENTS MEMORANDUM SECY-06-0069

PURPOSE:

The purpose of this paper is to inform the Commission of the results of the U.S. Nuclear Regulatory Commission (NRC) staff actions to identify existing and potential problems regarding the implementation of the "grandfather" provisions in the training and experience regulations in 10 CFR Part 35, and corresponding Agreement State requirements, as they relate to Medical Physicists (MPs), Authorized Medical Physicists (AMPs), and Radiation Safety Officers (RSOs). This paper does not identify any new commitments, resource implications, or recommendations for Commission action.

SUMMARY:

In Staff Requirements Memorandum (SRM)-SECY-06-0069, "Proposed Rule: Requirements for Expanded Definition of Byproduct Material," the Commission specifically directed the staff to conduct an outreach program with the Agreement States and with certain medical specialty certification boards to outline and explain the "grandfather" provisions and potential methods by which the training and experience regulations in 10 CFR Part 35 may be implemented, particularly as they relate to MPs. With regard to the Agreement States, the staff was directed

CONTACT: Ronald E. Zelac, Ph.D., FSME/MSSA
(301) 415-7635

to conduct an appropriate survey of the Agreement States to determine if there are specific problems to be resolved, and in particular as they relate to MPs. The SRM also directed the staff to document the results of these interactions in a paper submitted to the Commission and, if necessary, to offer recommendations for Commission action.

The staff has continued its discussions of the issue of authorizing MPs under the training and experience (T&E) requirements of 10 CFR Part 35 with representatives of medical specialty boards certifying MPs and with professional organizations representing MPs. The staff has also surveyed the Agreement States about these MP-related issues and offered recommendations to them on "grandfathering" and on implementing training and experience requirements for MPs. Finally, the staff prepared a Regulatory Issues Summary (RIS) on these matters that was distributed to NRC medical use licensees on December 7, 2006 and to MP professional organizations and certification boards for MPs on December 15, 2006; the RIS will also be distributed to Agreement State programs.

As a result of these activities, the staff has only identified one potential problem that necessitates NRC staff action: AMPs may not be identified on licenses and permits in some Agreement States by April 29, 2008, the deadline for required implementation of regulations compatible with the 2005 Part 35 T&E rule. After that date, a principal pathway for Agreement States to assess and approve the qualifications of MPs, the "certification pathway" to authorization, will become more restrictive, as only diplomates who were certified during a time period when their boards are recognized will be able to apply for authorization via the Agreement State-equivalents to 10 CFR Part 35.51(a), the "certification pathway." The staff actions to address this potential future problem are intended to accelerate the listing of MPs as AMPs on medical use limited-scope licenses and broad-scope-license permits in Agreement States that do not currently list MPs on licenses, thereby avoiding potential disruption in the delivery of health care involving sealed radioactive material sources used for therapeutic purposes. Some of the staff actions being taken are also intended to expand the number of MP applicants eligible to seek authorized status via the "certification pathway."

BACKGROUND:

On March 7, 2005, the Commission approved a final rule, amending Part 35 to modify T&E requirements. The rule was published in the *Federal Register* on March 30, 2005, (70 FR 16336) and became effective on April 29, 2005. The principal changes in the final rule revised the criteria that medical specialty certification boards must meet for their certification process to be recognized by NRC or Agreement States.[1] The rule also included additional revisions to other training and attestation requirements.

The criteria for recognition of a board's certification process and for approval of an MP as an AMP via the "certification pathway," are specified in 10 CFR Part 35.51(a). The criteria for

[1]Under the modified T&E requirements, board certification processes are now recognized for specified times, when criteria are met, rather than blanket recognitions.

approval of an MP as an AMP by evaluation of the individual's T&E, the "alternate pathway," are in 10 CFR Part 35.51(b). The criteria for recognition of a board's certification process and for approval of an MP as an RSO via the "certification pathway" are in 10 CFR Part 35.50(a)(2) and (c)(1).[2] The criteria for approval of an MP as an RSO by evaluation of the individual's T&E, the "alternate pathway," are in 10 CFR Part 35.50(b). The "grandfathering" provisions for experienced MPs, AMPs, and RSOs are in 10 CFR Part 35.57. This section indicates that those individuals who are identified on NRC or Agreement State licenses or permits before October 24, 2002, and between October 24, 2002, and April 29, 2005, need not comply with the training requirements of 10 CFR Part 35.50 or Part 35.51.

Following Commission direction, procedures for recognizing the certification processes of medical-specialty boards whose processes meet the criteria in the March 30, 2005, final rule were developed and posted on the NRC public web site, at: www.nrc.gov/materials/miau/med-use-toolkit/certif-process-boards.html. These procedures require each board that applies to indicate when the certification process being described for recognition was established (i.e., became effective).[3]

At its October 2005 meeting, and again at its April 2006 meeting, some members of the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) expressed concern about medical specialty certification board process recognitions having effective dates. The concern was that with effective dates, boards' diplomates certified prior to the dates specified would, if not "grandfathered" under 10 CFR Part 35.57, have to apply for authorized status via the "alternate pathway" and submit information describing their T&E. The ACMUI members expressing concern thought that all diplomates of boards having recognized certification processes should be able to apply for authorized status via "certification pathways," and that requiring any of these individuals to submit information describing their T&E, to apply via "alternate pathways," was unnecessarily burdensome.

At its April 2006 meeting, the ACMUI recommended that NRC contact one board, the ABR, requesting the Board to determine whether effective dates earlier than those it provided could be specified for recognition of its diagnostic radiology and radiation oncology certification processes for authorized users (AUs). The ACMUI did not extend its concern about this issue to include recommending actions involving specialty boards certifying MPs.

At each of these public meetings, similar concerns, focused on the available pathways to be authorized as AMPs and as RSOs for MPs certified by a board having a recognized certification

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[2]There are only a limited number of NRC-regulated medical uses that require an AMP.

[3]To-date, only one board providing certification for MPs under 10 CFR Part 35.51(a), the American Board of Radiology (ABR), has received recognition of its certification process. An application from a second specialty board, the American Board of Medical Physics (ABMP), has been received by NRC; staff is awaiting additional information from the ABMP to continue its review of the application. Also, to-date, two boards providing certification for MPs under 10 CFR Part 35.50(a)(2), the ABR and the American Board of Science in Nuclear Medicine (ABSNM), have received recognition of their certification processes.

All specialty-board certification processes recognized by NRC or Agreement States are listed on the NRC public web site at: www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.

process but certified before the effective date of the recognition and not "grandfathered" under 10 CFR 35.57, were voiced by representatives of the American Association of Physicists in Medicine (AAPM). Subsequently, in early May 2006, representatives of the AAPM and the ABR met with Commissioner Jaczko to express the same concerns. The meeting was shortly followed by a letter, dated May 10, 2006, from the AAPM to Commissioner Jaczko. The letter recommended revising the "grandfathering" provision in 10 CFR Part 35.57 to "grandfather" as AMPs all MP diplomates of the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP) for the modalities that they practiced as of October 24, 2005, the expiration date for 10 CFR Part 35 Subpart J, "Training and experience requirements," regardless of whether or not the diplomates were listed on NRC or Agreement State licenses or permits. The letter also recommended that 10 CFR Part 35.57 be revised to "grandfather" as RSOs all diplomates of certification boards that were previously listed in 10 CFR Part 35 Subpart J for an RSO, regardless of whether or not the diplomates were listed as RSOs on NRC or Agreement State licenses or permits, as long as they have relevant timely work experience and appropriate preceptor statements are submitted.

The staff discussed these issues raised by the ACMUI and by the AAPM with Commissioner Jaczko on May 17, 2006, and subsequently, on June 19, 2006, with Commissioners' Technical Assistants in a briefing requested by the Office of Commissioner Merrifield. As a result of these meetings, the Commission provided the direction to staff in SRM-SECY-06-0069, stated above. Note that the AAPM's recommendations were submitted in its letter, dated May 10, 2006, and were subsequently submitted to NRC as a Petition for Rulemaking, to amend 10 CFR 35.57, by letter to the Secretary of the Commission, dated September 10, 2006.

DISCUSSION:

The Commission-directed outreach program, to outline and explain the "grandfather" provisions and potential methods by which the T&E regulations in 10 CFR Part 35, may be implemented, particularly as it relates to MPs, has included continuation of ongoing discussions with representatives of certification boards (ABR and ABMP) and with representatives of stakeholder organizations (AAPM and American College of Medical Physics), representing certified MPs. This outreach has also included the issuance of, All-Agreement States Letter, STP-06-056, "Information Request: Listing Authorized Medical Physicists on Certain Byproduct Material Medical Use Licenses," (Enclosure 1). This Letter also provided a survey that solicited feedback to determine if there are specific problems to be resolved, particularly as they relate to MPs.

Through these interactions with certification boards, stakeholder organizations, and the Agreement States, three concerns of these stakeholders were apparent: (1) Some Agreement States are presently not listing MPs on licenses (an NRC issue of concern); (2) Not all certified MPs have a clear pathway to authorization as an AMP (an AAPM issue of concern); (3) Not all certified MPs have a clear pathway to authorization as a RSO (an AAPM issue of concern).

The staff conclusions reached on these issues, reasons for the conclusions, and actions taken to effect improvements are discussed below.

Issue of concern (1) - Some Agreement States are presently not listing MPs on licenses (an NRC issue of concern).

The responses to the NRC survey of Agreement States, noted above, indicated that 28 of the 34 Agreement States have been or are now listing MPs or AMPs on their limited-specific-use licenses. However, the six remaining Agreement States[4] indicated that they did not previously list MPs or AMPs on their licenses and are not doing so now.[5] These six Agreement States do intend to list AMPs on their licenses by 2008. The actions that NRC has taken to address this situation are discussed below.

A problem potentially impacting the future delivery of health care would exist if AMPs are not identified on medical use limited-scope licenses and broad-scope-license permits in all Agreement States by the April 29, 2008, deadline for Agreement States to have regulations compatible with the 2005 10 CFR Part 35 T&E rule. This situation may develop, in part, because, as noted above, the current medical use licensing practice in six Agreement States is to not list MPs or AMPs who are providing services to licensees authorized for use of teletherapy units, remote afterloader units, Gamma Knife® units, and Sr-90 sources for opthalmic treatments.[6]

After April 29, 2008, a principal pathway for Agreement States to assess and approve the qualifications of MPs associated with licensee use of these devices, the "certification pathway," will become more restrictive. After that date, only diplomates who were certified during a time period when their boards' certification processes are recognized will be able to apply for authorization via the Agreement State-equivalents to 10 CFR Part 35.51(a), the "certification pathway." Other diplomates, if not "grandfathered" by being listed on an Agreement State license or permit, will have to apply via the pathways and methods available to non-certified MPs, as described below. Therefore, after April 29, 2008, AMPs not being identified on Agreement State licenses and permits will become more problematic.

For many years, NRC has named MPs on licenses for teletherapy units, remote afterloader units, Gamma Knife® units, and Sr-90 eye applicators. In the 2002 revision of Part 35, NRC began identifying these MPs as AMPs. However, as noted above, the Agreement States have not uniformly been listing MPs on medical use licenses.

In its application for NRC recognition of its certification processes, the ABR specified that its process for MPs, under 10 CFR Part 35.51(a), certification in Therapeutic Radiologic Physics,

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[4]Kansas, Louisiana, Maryland, Mississippi, New Hampshire, and Tennessee.

[5]Note that the deadline for Agreement State implementation of regulations compatible with the 2005 Part 35 T&E rule is April 29, 2008. Until then, Agreement States can authorize (and list) MPs as MPs or AMPs under their existing, in some cases non-compatible, requirements. Individuals so-approved can assume responsibilities as authorized MPs at other licensees' facilities under NRC's notification provision (10 CFR 35.14) or equivalent regulations in some Agreement States.

The Part 35 T&E requirements are all Compatibility Category B, so Agreement State requirements should be essentially identical to those of the NRC. Also note that listing MPs and AMPs on Agreement State licenses is a voluntary action on the part of the Agreement States.

[6]NRC regulations in 10 CFR Part 35 and corresponding Agreement State regulations applicable to the therapeutic use of these sealed radioactive material sources and units require that an AMP be identified for these uses.

will become effective in June 2007. This means that MPs certified by the ABR before June 2007, and, presently, MPs certified by the ABMP, cannot apply to NRC, or to Agreement States that have revised their regulations to conform with the 2005 Part 35 T&E revision, for recognition as AMPs via the "certification pathway," in 10 CFR Part 35.51(a). Such individuals must seek recognition via the pathways and methods available to non-certified MPs, specifically: 1) the "grandfather provision pathway," in 10 CFR Part 35.57, if listed on NRC or Agreement State licenses, or on permits dated prior to April 29, 2005; 2) the "notification provision pathway," in 10 CFR Parts 35.2 and 35.14, if listed on NRC or Agreement State licenses or permits dated after April 29, 2005; or 3) the "alternate pathway" in 10 CFR Part 35.51(b).

For the "alternate pathway," the applicant must supply detailed information, to demonstrate conformance with the T&E requirements in 10 CFR Part 35.51(b) and the recentness-of-training requirements in 10 CFR Part 35.59, or equivalent Agreement State requirements. To MPs and other applicants for authorized status, the process of compiling the required information presently appears to be difficult because the optional-use NRC form which is available for documenting the detailed information on T&E, NRC Form 313A, "Medical Use Training and Experience and Preceptor Attestation," is designed to gather information for all applicants, and therefore is complicated. This situation is being addressed, as discussed below.

To address this issue of some Agreement States presently not listing MPs on licenses, NRC is strongly encouraging: 1) non-listed MPs to request being identified as AMPs on the Agreement State licenses or broad-scope-license permits for their present facilities; and 2) all Agreement States to specifically list AMPs in licenses authorizing the medical use of teletherapy units, remote afterloader units, Gamma Knife® units, and Sr-90 eye applicators, whenever license renewals, revisions, or amendments occur. These actions, initiated now, will prevent rushed efforts and backlogs in Agreement States not presently listing MPs, to list AMPs as April 29, 2008, approaches. Also, these actions will facilitate the review/approval process for those certified MPs who are not presently listed on licenses and for whom the "grandfather" provisions do not apply. Further, these actions will also facilitate relocation, when sought, to another facility by MPs who are practicing in Agreement State-licensed medical use facilities but are not listed on licenses or broad-scope-license permits.

Mechanisms that NRC is employing, for encouraging the actions that are mentioned above by non-listed MPs and by non-listing Agreement States, include the following:

- Issuance of All-Agreement States Letter, STP-06-056, "Information Request: Listing Authorized Medical Physicists on Certain Byproduct Material Medical Use Licenses," on June 22, 2006, (encouraging listing MPs on licenses); see Enclosure 1;

- Issuing a Regulatory Issue Summary (RIS-2006-26), "Training and Experience and Grandfather Provisions for Authorized Medical Physicists Under 10 CFR Part 35," on December 7, 2006, (encouraging MPs to be listed); see Enclosure 2;

- Providing copies of the above-mentioned RIS to MP professional organizations (AAPM, American College of Medical Physics), certification boards for MPs (ABR, ABMP, ABSNM), and Agreement States, and suggesting that members, diplomates, and medical licensees, respectively, be notified of the RIS; and,

- To alleviate the perceived difficulty for applicants applying for AMP status via the "alternate pathway," developing a new series of NRC Form 313A's that includes a simplified NRC Form 313A, "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR Part 35.51]." See Enclosure 3. Agreement States are not required to use the NRC Form 313A.

Additionally, to expand the number of applicants eligible to seek AMP status via the "certification pathway," the NRC staff is approaching boards certifying MPs to explore their willingness to identify from their records, upon requests from diplomates seeking AMP status, those individuals who were certified in years for which the boards' certification processes are not recognized but whose documented T&E satisfy the requirements in 10 CFR Part 35.51(a), the "certification pathway." Diplomates whose T&E satisfy these requirements would be issued revised certificates, or equivalent, indicating this fact. Several boards, including the ABR, that certify physicians have already agreed to carry out, or are considering, similar actions for their diplomates seeking AU status.

Through these efforts, NRC staff expects that the potential future problem in some Agreement States, of AMPs not being identified on licenses and permits by April 30, 2008, will be avoided.

Issue of concern (2) - Not all certified MPs have a clear pathway to authorization as AMP (an AAPM issue of concern).

As noted above, medical specialty certification board process recognitions for the current 10 CFR Part 35 have effective dates. The concern expressed by AAPM is that with effective dates for recognition of the boards' certification processes, boards' diplomates certified as MPs prior to the dates specified would, if not "grandfathered" as AMPs under 10 CFR Part 35.57, have to apply for authorized status as AMPs via the "alternate pathway" in 10 CFR Part 35.51(b), and submit information describing their T&E.

The staff does not agree that this concern about limited "grandfathering" of MPs to AMP status (some certified MPs not being able to apply for authorization via the "certification pathway") is a serious issue, for the following reasons.

(1) Those MPs practicing and named on an NRC or Agreement State license or permit issued before October 24, 2002, or between October 24, 2002, and April 29, 2005, are "grandfathered" as AMPs under the provisions of 10 CFR Part 35.57(a).

(2) MPs can still seek authorized status via the "alternate pathway." "Certification pathways" exist and may expand as more boards, such as the ABMP, are recognized. In the 13 months since 10 CFR Part 35 Subpart J expired, there have not been problems reported by the Regions with MPs becoming authorized in NRC-regulated states. Also, some of the Agreement States have enacted their compatible equivalents to NRC's current T&E requirements to assess T&E of applicants. In these Agreement States, operating using their revised T&E requirements, no problems have been reported with MPs becoming authorized.

(3) Except for Sr-90 use, NRC licensure has long required listing the name of the MP. Also, 28 of the 34 Agreement States (82 percent) currently list MPs on licenses. The issue/problem

involves the six Agreement States that have not been listing medical physicists on licenses issued by them. As noted above, there is time to effect a solution.

(4) There are only a limited number of medical uses in NRC's regulations that require an AMP. The regulatory use of the term AMP includes MPs only for the following medical uses: Sr-90 eye applicators, remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery (Gamma Knife® units. Accordingly, the overall availability of MP services to NRC and Agreement State medical use licensees will not be significantly affected by some certified MPs not being able to apply for AMP status via the "certification pathway."

(5) There are only approximately 100 Sr-90 eye applicators, 765 remote afterloader units, 12 teletherapy units, and 109 Gamma Knife® units licensed in the U.S. NRC licenses about 260 of these devices, and the remaining 726 devices are licensed by Agreement States. Accordingly, the number of licensees with requirements for AMP services, approximately 1000, is not large, compared to the approximately 6000 total number of U.S. medical use licensees.

Issue of concern (3) - Not all certified MPs have a clear pathway to authorization as RSO (an AAPM issue of concern).

As noted previously, medical specialty certification board process recognitions have effective dates. The concern expressed by AAPM is that with effective dates, boards' diplomates certified prior to the dates specified would, if not "grandfathered" under 10 CFR Part 35.57, have to apply for authorized status as RSOs via the "alternate pathway" in 10 CFR Part 35.51(b), and submit information describing their T&E.

The staff does not agree that this concern about limited "grandfathering" of MPs to RSO status (some certified MPs not being able to apply for authorization via the "certification pathway") is a serious issue, for the following reasons.

(1) Anyone seeking RSO status must submit credentials for review, because a license amendment must be obtained before an individual can begin work as an RSO. There are no automatic authorizations for RSOs based on certifications from boards recognized under 10 CFR Part 35. This contrasts with MPs certified by boards with MP certification processes recognized under 10 CFR Part 35 being able to begin work as AMPs under the license amendment exception provision of 10 CFR Part 35.13(b)(3) and the notification provision of 10 CFR Part 35.14(a).

(2) There are presently NRC-recognized "certification pathways" to RSO for all three main types of certified MPs (therapeutic, diagnostic, nuclear medicine),[7] so the pool of certified MPs that can apply for authorization as RSO via "certification pathways" is larger than if only certified MPs qualified to be AMPs could apply via these pathways. Additionally, the certification processes of additional boards satisfying the requirements in 10 CFR Part 35.50(a)(2) or (c)(1) may be recognized. Such additional recognitions may provide additional time periods of certification for which certified MPs seeking RSO authorization can apply via "certification pathways."

[7] 10 CFR Part 35 and equivalent regulations of Agreement States only have requirements for MPs as AMPs that are associated with the therapeutic use of some sealed sources and devices.

(3) For MPs seeking RSO authorization via "certification pathways" [10 CFR Part 35.50 (a)(2) or (c)(1)] diplomates of any specialty board whose certification process in medical physics has been recognized by NRC or an Agreement State can supervise their required practical training and/or work experience; the certified supervisor does not have to be an AMP or an RSO, and the supervisor's certification does not have to have been obtained in a year that the specialty board's certification process was recognized. Therefore, there are ample numbers of certified MPs to serve as supervisors of the practical training and/or work experience required for individuals seeking certification by boards with recognized certification processes.

(4) There is a pathway to RSO authorization, 10 CFR Part 35.50(c)(2), based on having achieved AMP status, regardless of which pathway, "certification" or "alternate," was followed to achieve that status.

(5) Besides the "certification pathway" to RSO status, there are also other pathways, as discussed above: the "grandfather provision pathway; and the "alternate pathway." Therefore, a certified MP not being able to apply via the "certification pathway" does not "disenfranchise" him or her.

(6) As response to comments received from some stakeholders, the "alternate pathway" available to RSO status is not a lesser pathway; all RSOs for a given use are considered by NRC as equally capable of carrying out their responsibilities.

Additionally, as discussed above for AMPs:

(1) To expand the number of applicants eligible to seek RSO status via the "certification pathway," the NRC staff is approaching boards certifying MPs to explore their willingness to identify from their records, upon requests from diplomates seeking RSO status, those individuals who were certified in years for which the boards' certification processes are not recognized but whose documented T&E satisfy the requirements in 10 CFR Part 35.50(a)(2) or (c)(1), the "certification pathways" for MPs to RSO. Diplomates whose T&E satisfy these requirements would be issued revised certificates, or equivalent, indicating this fact. As noted above, several boards that certify physicians have agreed to or are considering similar actions for their diplomates seeking AU status.

(2) The new series of NRC Form 313As that staff is developing includes the simplified NRC Form 313A, "Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR Part 35.50]," for possible use by those individuals applying for RSO status via the "certification pathway" and the "alternate pathway;" see Enclosure 4. The revised form will be made available as soon as Office of Information Services clearance is received.

Accordingly, the staff believes that the only actions required to address the issue of RSO "grandfathering" are the vehicles and mechanisms that NRC is employing for encouraging non-listed MPs to seek AMP status and for encouraging non-listing Agreement States to list AMPs.

CONCLUSION:

The staff actions to accelerate the listing of MPs on Agreement State medical use limited-scope licenses and broad-scope-license permits, and to expand the number of applicants eligible to

seek AMP and RSO status via the "certification pathway," are expected to adequately address the currently identified problem areas/concerns associated with full implementation of the 10 CFR Part 35 T&E requirements.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

/RA MVirgilio acting for/

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. All-Agreement States Letter (STP-06-056), "Information Request: Listing Authorized Medical Physicists on Certain Byproduct Material Medical Use Licenses," ML061740148
2. Regulatory Issue Summary (RIS-2006-26), "Training and Experience and Grandfather Provisions for Authorized Medical Physicists Under 10 CFR Part 35"
3. NRC Form 313A, "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR Part 35.51]"
4. NRC Form 313A, "Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR Part 35.50]"

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