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UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE August 15, 2014

NUMBER OF PAGES 14

SEND TO Leon Kinasiewicz, M.D., Radiation Safety Officer, - St. Francis Hospital (NRC License 21-1648-01)

LOCATION Escanaba, Michigan

FAX NUMBER (906) 789-4489

▼ VERIFY BY CALLING

FROM: Bill Reichhold (Sender)

TELEPHONE NUMBER (630) 829-9839

FAX NUMBER (630) 515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE See accompanying documents.



UNITED STATES NUCLEAR REGULATORY COMMISSION

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NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank You.

The following additional information is needed to complete the review your request to add Dr. Stephen M. Manier as the new Radiation Safety Officer (RSO).

Since you wish to add a new RSO, please complete the NRC FORM 313A (RSO). See accompanying form. You may obtain a copy of the NRC 313A (RSO) FORM at the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(rso).pdf.

It appears you wish to follow the "Authorized User Identified on a NRC License" pathway to add a new Radiation Safety Officer. Please see the "marked" copy of the guidance information for completing the NRC 313A Series of Forms and the "marked" copy of the NRC FORM 313A (RSO). You may obtain a complete copy of the guidance information at the NRC website at: http://www.nrc.gov/materials/miau/med-use-toolkit/licensing-guidance-form313a.pdf.

You may wish to use a "clean" copy of the NRC FORM 313A (RSO) when you submit the additional information to add Dr. Stephen M. Manier as the new Radiation Safety Officer (RSO). Again, you may obtain a copy of the NRC 313A (RSO) FORM at the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(rso).pdf.

Please send a facsimile (630-515-1078) of your response to the above within 14 days and state, Response to Control 584543. Please include a cover letter on company letterhead, dated and signed (signed by an individual who is authorized to sign official documents on behalf of the licensee) with your response letter. Please call me at 630-829-9839 if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this facsimile and the attached documents will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

From the desk of:

Bill Reichhold

Licensing Guidance for using the NRC FORM 313A Series of Forms January 2008

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Authorized Medical Physicist, or Authorized Nuclear Pharmacist

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Radiation Safety Officer

An applicant or licensee who is adding an experienced authorized user (AU) for medical uses, authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or Radiation Safety Officer (RSO) to its medical use license or application only needs to provide evidence that the individual is listed on a medical use license issued by the NRC or Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC master material broad-scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 10 CFR 35.59. When adding an experienced ANP to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad-scope license, or Master Materials License medical broad-scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Experienced Physicians, Podiatrists, Dentists, Nuclear Pharmacists, Medical Physicists, and Radiation Safety Officers Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Radium-226, or Both, for Medical or Nuclear Pharmacy Uses.

In implementing the EPAct, the NRC "grandfathered" physicians, podiatrists, dentists, medical physicists, and nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium-226 (Ra-226), or both, for medical or nuclear pharmacy uses, before or under the NRC waiver of August 31, 2005, when using these materials for the same uses. These individuals, as well as individuals that performed RSO duties only for uses of accelerator produced radionuclides or discrete sources of Ra-226 at medical or nuclear pharmacy facilities before or during the effective period of the waiver, do not have to meet the requirements of 10 CFR 35.59, or the training and experience requirements in 10 CFR Part 35, Subparts B, D, E, F, and G.

The applicant or licensee that is adding one of these experienced individuals to its medical use license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, or both, for medical or nuclear pharmacy uses before or during the effective period of the waiver and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or non-Agreement State license or permit authorizing these materials for the requested uses.

III. Applications that Include Individuals for New Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist or Radiation Safety Officer Recognition by NRC

Applicants should submit the appropriate completed form in the NRC Form 313A series to show that the individuals meet the correct training and experience criteria in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For the applicant's convenience, the NRC Form 313A series has been separated into six separate forms. The forms are NRC FORM 313A (RSO) for the Radiation Safety Officer; NRC FORM 313A (AMP) for the authorized medical physicist; NRC FORM 313A (ANP) for the authorized nuclear pharmacist; NRC FORM 313A (AUD) for the authorized user of the medical uses included in 10 CFR 35.100, 35.200, and/or 35.500; NRC FORM 313A (AUT) for the authorized user for the medical use included in 10 CFR 35.300; and NRC FORM 313A (AUS) for the authorized user for the medical uses included in 10 CFR 35.400 and/or 35.600.

There are two primary training and experience routes to qualify an individual as a new AU, AMP, ANP, or RSO. The first is by means of certification by a board recognized by NRC and listed on the NRC Web site as provided in 10 CFR 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a). Preceptor attestations must also be submitted for all individuals to qualify under 10 CFR Part 35, Subparts B and D through H. Additional training may also need to be documented for RSOs, AMPs, and AUs under 10 CFR 35.600.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H. In some cases there may be additional training and experience routes for recognized AUs, ANPs, or RSOs to seek additional authorizations.

IV. Recentness of Training

The required training and experience, including board certification, described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience for physicians include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use,
- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization.
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization, and
- For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

V. General Instructions and Guidance for Filling Out NRC Form 313A Series

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple forms in the NRC Form 313A series or fill out some sections more than once. For example, an applicant that requests a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO, should provide three completed NRC Form 313A series forms (i.e., NRC Form 313A (RSO), NRC Form 313A (AUD) and NRC Form 313A (AUT)). Also, if the applicant requests that a physician be authorized for both high doserate remote afterloading and gamma stereotactic radiosurgery under 10 CFR 35.600, only one form, NRC Form 313A (AUS) needs to be completed, but one part (i.e., "Supervised Work and Clinical Experience") must be filled out twice.

To identify an Agreement State license, provide a copy of the license. To identify a Master Materials License permit, provide a copy of the permit. To identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad-scope license or broad-scope permit of a Master Materials License, provide a copy of the permit issued by the broad-scope licensee/permittee. Alternatively, provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following:

| | (name of supervising individual or pr | receptor) is authorized under | |
|-----|---------------------------------------|-------------------------------|----|
| | (name of licensee/permittee) b | road-scope license number | to |
| use | (materials) during(t | time frame)." | |

INTRODUCTORY INFORMATION



Name of individual

Provide the individual's complete name so that NRC can distinguish the training and experience received from that received by others with a similar name.

Note: Do not include personal or private information (e.g., date of birth, Social Security Number, home address, personal telephone number) as part of your qualification documentation.

State or territory where licensed

The NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, as well as licensed in the practice of dentistry, podiatry, or pharmacy, respectively (see definitions of "physician", "dentist", "podiatrist", and "pharmacist" in 10 CFR 35.2).



Requested Authorization(s).

Check all authorizations that apply and fill in the blanks as provided.

Part I. Training and Experience

There are always multiple pathways provided for each training and experience section. Select the applicable one.

Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

The NRC Form 313A series Part II - Preceptor Attestation has multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and competency to function independently, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each form in the NRC 313A series.

VI. RADIATION SAFETY OFFICER - Specific Instructions and Guidance for Filling Out NRC Form 313A (RSO)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of four methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of specific radiation safety training for all types of use on the license, and a completed preceptor attestation). As indicated on the form, additional information is needed if the board certification or radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above.

Provide the requested information (i.e., documentation of specific radiation safety training (complete the table in 3.c) and a completed preceptor attestation in Part II). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Structured Educational Program for Proposed New Radiation Safety Officer

As indicated on the form, additional information is needed if the training, supervised radiation safety experience, and specific radiation safety training was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. The individual must have completed 1 year of full-time radiation safety experience under the supervision of an RSO. This is documented in Section 3.b by providing the ranges of dates for supervised radiation safety experience. If there was more than one supervising individual, identify each supervising individual by name and provide his/her qualifications.

Provide the requested information (i.e., documentation of specific radiation safety training for each use on the license (complete the table in 3.c)). Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Item 4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist Identified on the Licensee's License

Provide the requested information (i.e., the license number and documentation of specific radiation safety training for each use on the license (complete the table in 3.c)). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation for the new proposed RSO's training or identification on the license as an AU, AMP, or ANP is in the first section.

The attestation for the specific radiation safety training is in the second section.

The attestation for the individual's competency to function independently as an RSO for a medical use license is in the third section.

The fourth and final section requests specific information about the preceptor's authorization as an RSO on a medical use license in addition to the preceptor's signature.

The preceptor for a new proposed RSO must fill out all four sections.

The preceptor for an RSO seeking authorization to be recognized as an RSO for the additional medical use(s) must fill out the second, third, and fourth sections.

VII. AUTHORIZED MEDICAL PHYSICIST - Specific Instructions and Guidance for Filling Out NRC Form 313A (AMP)

See Section V, "General Instructions and Guidance for Filling Out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of device-specific training in the table in 3.c, and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 2. Current Authorized Medical Physicist Seeking Additional Uses(s) Checked above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.c) and complete the Preceptor Attestation in Part II). As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Training and Experience for Proposed Authorized Medical Physicist

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a. Submit documentation of a graduate degree (for example, a copy of a diploma or transcript from an accredited college or university).

NRC FORM 313A (RSO) (05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

| RADIATION SAFETY OFFICE AND PRECEPTO | R TRAINING AND EXPERIENC OR ATTESTATION | CE APPROVED E EXPIRES: (05 | BY OMB: NO. 3150-01: 5/31/2015) |
|---|---|-------------------------------|------------------------------------|
| [10 CF | R 35.50] | | |
| lame of Proposed Radiation Safety Officer | | | |
| Requested Authorization(s) The license authorization | orizes the following medical uses (che | eck all that apply): | |
| 35.100 35.200 35.300 | 35.400 35.500 | 35.600 (remote | e afterloader) |
| 35.600 (teletherapy) 35.600 | (gamma stereotactic radiosurgery) | 35.1000 (|) |
| | I TRAINING AND EXPERIENCE ect one of the four methods below) | | |
| Training and Experience, including board ce application or the individual must have obtain and experience was completed. Provide dat to the uses checked above. | rtification, must have been obtained wheel related continuing education and | experience since th | ne required training |
| 1. Board Certification | | | |
| a. Provide a copy of the board certification | on. | | |
| b. Use Table 3.c. to describe training in all types of medical use on the license. | radiation safety, regulatory issues, an | d emergency proce | edures for |
| c. Skip to and complete Part II Preceptor | r Attestation. | | |
| | OR | | |
| 2. Current Radiation Safety Officer See Officer for the Additional Medical Us | king Authorization to Be Recognize es Checked Above | ed as a Radiation | Safety |
| a. Use the table in section 3.c. to describ procedures for the additional types of me | edical use for which recognition as RS | | ergency |
| b. Skip to and complete Part II Precepto | | | |
| | OR | | |
| 3. <u>Structured Educational Program for</u> a. Classroom and Laboratory Training | Proposed Radiation Safety Officer | • | |
| Description of Training | Location of Training | Clock Hours | Dates of Training* |
| Radiation physics and instrumentation | | | |
| Radiation protection | | | |
| Mathematics pertaining to the use and measurement of radioactivity | | | |
| Radiation biology | | | |
| Radiation dosimetry | | | |
| | Total Hours of Training: | | |
| | | | |

(05-2012)

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

| Description of Experience | Location of Training/ License or Permit Number of Facility | Dates of Training* |
|---|---|-----------------------|
| Shipping, receiving, and performing related radiation surveys | | |
| Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides | | |
| Securing and controlling byproduct material | | |
| Using administrative controls to avoid mistakes in administration of byproduct material | | |
| Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures | | |
| Using emergency procedures to control byproduct material | | |
| Disposing of byproduct material | | |
| Licensed Material Used (e.g., 35.100, 35.200, etc.)+ | | |

⁺ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

| Structured Educational Program for Proposed R | adiation Safety Officer (continued) | | | |
|---|---|--|--|--|
| b. Supervised Radiation Safety Experience (contin | ued) | | | |
| (If more than one supervising individual is necessory copies of this section.) | sary to document supervised work experi | ence, provide multip | | |
| Supervising Individual | License/Permit Number listing supervisi Radiation Safety Officer | License/Permit Number listing supervising individual as a Radiation Safety Officer | | |
| This license authorizes the following medical uses: | | | | |
| ☐ 35.100 ☐ 35.200 ☐ 35.300 | 35.400 | | | |
| 35.500 35.600 (remote afterloader) | 35.600 (teletherapy) | | | |
| 35.600 (gamma stereotactic radiosurgery) | 35.1000 () |) | | |
| use on the license. Description of Training | Training Provided By | Dates of Training* | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses | | | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.300 uses | | | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.400 uses | | | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses | | | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses | | | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses | | | | |
| Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s): | | | | |

2. Structured Educational Program for Proposed Radiation Safety Officers

Name of Proposed Radiation Safety Officer

program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

has satisfactorily completed a structural educational

I attest that

| NRC FORM 313A (RSC (05-2012) | U.S. NUCLEAR REGULATORY COMMISSION |
|--|--|
| ` ' | FETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) |
| Preceptor Attesta | tion (continued) |
| First Section (con Check one of the | |
| 3. Additiona | al Authorization as Radiation Safety Officer |
| I attest that | is an |
| | Name of Proposed Radiation Safety Officer |
| Aut | horized User Authorized Nuclear Pharmacist |
| Aut | horized Medical Physicist |
| aspect | ed on the Licensees license and has experience with the radiation safety s of similar type of use of byproduct material for which the individual has ion Safety Officer responsibilities |
| | AND |
| Second Section Complete for all | check all that apply): |
| I attest that | has training in the radiation safety, regulatory issues, and |
| emergency pr | Name of Proposed Radiation Safety Officer ocedures for the following types of use: |
| 35.100 | occurred to the concurring types of account |
| 35.200 | |
| 35.300 | oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required |
| 35.300 | oral administration of greater than 33 millicuries of sodium iodide I-131 |
| 35.300 | parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required |
| 35.300 | parenteral administration of any other radionuclide for which a written directive is required |
| 35.400 | |
| 35.500 | |
| 35.600 | remote afterloader units |
| 35.600 | teletherapy units |
| 35.600 | gamma stereotactic radiosurgery units |
| 35.1000 | emerging technologies, including: |
| _ | |

| RADIATION SAFETY OFFIC | ER IRAINING AND E | EAPERIENCE AND PR | RECEPTOR ATTESTATION | NA (CONTINUE |
|---------------------------------|-------------------------------|--------------------------|-----------------------------|--------------|
| | | AND | | |
| Third Section | | | | |
| Complete for ALL | | | | |
| | | | | |
| I attest that | osed Radiation Safety Officer | has achieved a leve | l of radiation safety knowl | eage |
| | | | | |
| sufficient to function indepe | ndently as a Radiation | n Safety Officer for a m | iedical use licensee. | |
| | | | | |
| | | | | |
| Fourth Section | | | | |
| Complete the following for Pre | ceptor Attestation a | nd signature | | |
| | | | | |
| I am the Radiation Safety Offic | er for | Name of | f Facility | |
| License/Permit Number: | | | | |
| License/Femilit Number. | | | | |
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