



CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU Mark Gomez Individual listed as contact on NRC Form 313		DATE OF CONTACT 05/31/2019	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING	
E-MAIL ADDRESS mark.gomez@roush.com		TELEPHONE NUMBER (734) 779-7266		
ORGANIZATION Roush Industries, Inc., 12447 Levan Rd., Livonia, MI 48150		DOCKET NUMBER(S) 030-39165		
LICENSE NAME AND NUMBER(S) N/A		MAIL CONTROL NUMBER(S) 611716		

SUBJECT
Additional Information Request concerning the licensee's request for a U.S. NRC radioactive materials license, including to allow possession and use of germanium-69 in oil, for testing of engines

SUMMARY AND ACTION REQUIRED (IF ANY)

This record concerns the licensee's March 12, 2019 application (NRC Accession No. ML19084A258) requesting a radioactive materials license for the possession and use of tetra-alkylated germanium-69 compounds in engine oil, for testing of those engines.

Upon review, we have noted that the application omits information requested in the NRC's NUREG 1556 Vol. 7, rev. 1, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," guidance volume. As discussed, please see attached for information needed to complete our review of your request.

If available, please provide the requested information within 14 days of this message (on or before June 14, 2019). Include a signed and dated cover letter transmitting your response. Submission of your response as a pdf file attached to an email or via facsimile to 630-515-1078 will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. If unavailable, you may withdraw your application and would be permitted to resubmit at a later date without prejudice for resubmission.

Thank you for your prompt attention to this matter.

NAME OF PERSON DOCUMENTING CONVERSATION
Sara A. Forster, M.S., Health Physicist, Materials Licensing Branch, DNMS, RIII office, sara.forster@nrc.gov

SIGNATURE <i>Sara A. Forster</i>	DATE OF SIGNATURE 05/31/2019
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CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

MAIL CONTROL NUMBER(S)

N/A

611716

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

ADDITIONAL INFORMATION NEEDED FOR CONTINUED REVIEW

I. For general resubmission of the application:

- (1) Please resubmit the NRC Form 313, signed and dated by a Senior Management official from Roush Industries, Inc., or other individual designated to sign on that official's behalf;
- (2) Please include the licensee's mailing address as submitted in the March 12, 2019 application;
- (3) Please confirm that the licensee's sole address where materials will be used or stored is 36630 Commerce St., Livonia, MI 48150.
- (4) Please confirm that all remaining new license application fees (\$5700 still due as of April 3, 2019) have been submitted to the NRC. Note that if license application cannot be completed in time, fees may increase in accordance with the "Schedule of Materials Fees" provided in Category 3.M. for Program Code "Research and Development," in Title 10 of the *Code of Federal Regulations* Section 170.31.
- (5) Please provide a Taxpayer Identification Number (TIN) using NRC Form 531, "Request for Taxpayer Identification Number," in accordance with the Debt Collection Improvement Act of 1996."

II. For the authorization for possession and use of germanium-69 as tetra-alkylated germanium-69 in engine oil:

- (1) Please confirm that the only requested radionuclide is germanium-69, with a requested form of tetra-alkylated compounds in oil;
- (2) For germanium-69 to be used at the licensee's facilities, please describe (a) maximum quantity to be received per shipment, in microcuries (μCi), megabecquerels (MBq), or other appropriate unit; (b) maximum concentration to be received per shipment, in microcuries per milliliter ($\mu\text{Ci/mL}$) and/or MBq/mL; and (c) maximum overall possession limit in millicuries (mCi) or MBq;
- (3) Please describe how the germanium-69 containing oil will be used, including how it will be transferred to and removed from the engines to be tested. Include any special handling equipment, containment, shielding, and other information pertinent to protection from radiation hazards and minimization of contamination.

III. For listing Individual(s) Responsible for Radiation Safety Program and their Training and Experience:

- (1) Please provide the name of a Radiation Safety Officer (RSO) who has been appointed by management to oversee the program, and attach documentation of that individual's training and experience sufficient for that individual to be listed on the license. Sample RSO training criteria may be found in NRC's NUREG 1556 Vol. 7, rev. 1, Section 8.7.1, pp. 8-13 to 8-16;

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

MAIL CONTROL NUMBER(S)

N/A

611716

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

III. For listing Individual(s) Responsible for Radiation Safety Program and their Training and Experience (continued):

- (2) Please provide a copy of a Memorandum of Understanding/Delegation of Authority (MOU/DOA) document, signed and dated by both the licensee's Management Representative and the RSO. At a minimum, the MOU/DOA should indicate the RSO's responsibilities and authority for the licensed program and that RSO's acceptance of those duties. Sample RSO duties together with a sample MOU/DOA form may be found in NRC's NUREG 1556 Vol. 7, rev. 1, Appendix E, pp. E-1 to E-3. A copy of this appendix is attached for your reference; and
- (3) Please provide the name of at least one Authorized User (AU) for this license, and attach documentation of the training and experience for each AU to be listed on the license. Sample AU training criteria may be found in NRC's NUREG 1556 Vol. 7, rev. 1, Section 8.7.2, pp. 8-16 to 8-18.

IV. For describing your radiation safety training program, please provide details:

- (1) topics covered,
- (2) groups of workers to be trained,
- (3) how training will be assessed - including criteria for determining whether training is adequate,
- (4) qualifications of instructors,
- (5) method of training, and
- (6) frequency of training;

V. For authorizing possession and use of byproduct material at the location listed in your application:

- (1) Please provide a description for each area where licensed material will be used or stored - including of used shipping containers and decay-in-storage waste, as applicable - in accordance with NRC's NRC's NUREG 1556 Vol. 7, rev. 1, (a) Section 8.9, pp. 8-19 to 8-21, (b) Appendix C, Item 9, pp. C-2 to C-3, and/or (c) Appendix G, pp. G-1 to G-3, as applicable;
- (2) Your response should include a diagram of the area where the material will be used or stored, showing street address, room number, any physical barriers (doors, walls, windows, etc.), and scale of the area (i.e. 100 sq. ft.) highlighted in the submitted facility diagrams;
- (3) Your response should also list specific use and storage areas (e.g. lab benches, ventilated hoods, locked cabinets, refrigerators, etc.), within the area shown;
- (4) Please describe how the area is secured (key, keycard, code, etc.), with a description of individuals (Radiation Safety Officer (RSO), Authorized Users (AUs), housekeeping, etc.) who will be able to access, or who will routinely access, the requested area; and
- (5) Finally, please describe any safety features (handling equipment, spill containment, etc.) available location where radioactive material will be used and stored.

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

MAIL CONTROL NUMBER(S)

NA

611716

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

V. For describing your Radiation Safety program, in accordance with guidance provided in NUREG 1556, Vol. 7, rev. 1, Items 8.10.2 through 8.10.7, pp. 8-22 through 8-45:

(1) Concerning Item 8.10.2 - Radiation Monitoring Instruments (continued):

(a) Please describe instrumentation that will be used to perform required surveys. **and**

(b) Concerning instrument description, please confirm the statement:

"We will use instruments that meet the radiation monitoring instrument specifications published in accordance with the survey frequencies and contamination levels published in Appendix I in NUREG 1556, vol. 7, rev. 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.' We reserve the right to upgrade our survey instruments as necessary."

(c) Concerning instrument calibration, please either confirm the statement:

"Instruments [required for the program] will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration." **or,**

If the licensee will be performing its own instrument calibrations for instruments used in required surveys, please either:

(i) Confirm the statement:

*"We will implement the model radiation survey meter calibration program published in Appendix I in NUREG 1556, vol. 7, rev. 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.'" **or***

(ii) Submit equivalent procedures for instrument calibration.

(2) Concerning Item 8.10.3 - Material Receipt and Accountability - please confirm the statement:

"We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."

(3) Concerning Item 8.10.4 - Occupational Dose - please confirm the statement:

"We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

MAIL CONTROL NUMBER(S)

NA

611716

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

V. For describing your Radiation Safety program, in accordance with guidance provided in NUREG 1556, Vol. 7, rev. 1, Items 8.10.2 through 8.10.7, pp. 8-22 through 8-45 (continued):

(4) Concerning Item 8.10.6 - Safe Use of Radionuclides, Security, and Emergency procedures - either:

(a) Please confirm the statement:

"We will develop, implement, and maintain procedures for safe use, security and emergencies." or

(b) Please confirm the statement:

"We will adopt the procedures for the safe use of radionuclides, security and emergencies as published in Appendix L in NUREG -1556, Volume 7, Revision 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope." or

(c) Provide procedures for safe use of radionuclides, security of materials, and emergencies.

(5) Concerning Item 8.10.7 - Surveys and Leak Tests - please provide the following:

(a) Confirm that no non-exempt sealed sources will be used or stored, under the license; **and**

(b) And either confirm the statement:

"We will survey our facility and maintain contamination levels in published in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG 1556, vol. 7, rev. 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope;" or

Submit a description of an alternate radiation survey program, including survey frequencies and contamination levels, to evaluate a radiological hazard.

VI. For describing your waste management program:

(1) Please describe how decay-in-storage waste will be managed and disposed of at the end of the decay period (i.e. returned to manufacturer, decay-in-storage, etc.); **and**

(2) Please confirm that the applicant will not either compact or incinerate radioactive waste; **and**

(3) Please confirm one of the two statements, below:

(a) *"We will use the model waste procedures published in Appendix P in NUREG 1556, vol. 7, rev. 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.'*

(b) *"We will use the decay-in-storage model waste procedures published in Appendix P in NUREG -1556, Vol. 7, rev. 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.'*

8.7 Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

8.7.1 Radiation Safety Officer

Regulations: 10 CFR 30.33(a)(3), 10 CFR 30.34(e), 10 CFR 40.32(b), 10 CFR 70.22(a)(6)

Criteria: The Radiation Safety Officer's (RSO's) training and experience should be applicable to and generally consistent with the types and quantities of licensed material listed on the license for which the individual's authorization as an RSO is requested.

Discussion: The person responsible for the radiation protection program is the RSO. The RSO is key to overseeing and ensuring safe operation of the licensee's radiation protection program. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations that he or she considers unsafe. He or she should have sufficient time and commitment from management to fulfill his or her duties and responsibilities to ensure that radioactive materials are used in a safe manner, approved radiation safety procedures are being implemented, and the required records of licensed activities are maintained. Typical RSO duties are illustrated in Figure 8-4 and described in Appendix E of this NUREG. The NRC requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO. Appendix E of this NUREG also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO.

The RSO should have, at a minimum, (i) a college degree at the bachelor's level or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed activities.

Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection and measurement instrumentation
- biological hazards of exposure to radiation (appropriate to types and forms of byproduct material to be used)
- NRC regulatory requirements and standards commensurate with the uses proposed by the applicant
- hands-on use of radioactive materials

Experience should include the following areas:

- planning and conducting evaluations, surveys, and measurements similar to those that the licensee's radiation safety program requires
- use of licensed materials similar in types, forms, and quantities to those proposed for use under the license

Request for information, continued, p. 6 of 11

Radiation Safety Officer Duties and Responsibilities

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety, security, and compliance with both U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and the conditions of the license (see Figure 8-5). Typically, these duties and responsibilities include the following:

- Ensure that licensed material that the licensee possesses is limited to the types and quantities of byproduct material listed on the license.
- Maintain documentation demonstrating that the dose to individual members of the public does not exceed the limit specified in Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 20.1301.
- Ensure security of radioactive material.
- Post documents as required by 10 CFR Parts 19.11, "Posting of notice to workers," and 10 CFR 21.6, "Posting requirements."
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements.
- Ensure that radiation exposures are "as low as is reasonably achievable" (ALARA).
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with the NRC and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material before use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping of waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.

Request for information, continued, p. 7 of 11

- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radionuclides possessed under the license, and limit the quantity to the amounts that the license authorizes.
- Immediately terminate any unsafe condition or activity found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by 10 CFR 30.51, "Records," and 10 CFR Part 20, Subpart L, "Records."
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all radioactive materials users are properly trained.
- Perform periodic audits of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license (e.g., leak tests; inventories; use limited to trained, approved users); the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are ALARA, in accordance with 10 CFR 20.1101; and required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change, are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all radiation workers, including ancillary personnel.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or 10 CFR Part 20 limits are investigated and reported to the NRC and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and keep up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.
- Develop, implement, maintain, and distribute, as appropriate, up-to-date operating, emergency, and security procedures.

Request for information, continued, p. 8 of 11

Model Delegation of Authority for Radiation Safety Officer

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed radiation safety officer and are responsible for ensuring the safe and secure use of radiation. You are responsible for managing the Radiation Protection Program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

8.7.2 Authorized User

Regulations: 10 CFR 20.1101(b), 10 CFR 30.33(a)(3), 10 CFR 40.32, 10 CFR 70.22

Criteria: Authorized users (AU) must have adequate training and experience with the types and quantities of licensed material they propose to use.

Discussion: An AU (also known as "principal investigator," "permit holder," "source custodian," or by other licensee designations) is an individual whose training and experience have been reviewed and approved by the NRC, who is named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements (see Figure 8-5). The AU is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

AUs must have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely. Training for AUs should include: maintaining security of, and controlling access to, licensed material; and responding appropriately to events or accidents involving licensed material to prevent the spread of contamination.

- (1) Please provide the names of proposed AUs and a description of training that each proposed AU has had (formal training courses; hands-on training; RSO training courses; etc.) in:

An AU should have (i) a college degree at the bachelor's level or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to the types and forms of byproduct material to be used)

- (2) For each proposed AU, please provide (i) details for the individual's college or post-college degree (e.g. what the degree was, the individual's major, the conferring institution, and the date on which the degree was conferred); and (ii) details for the individuals radiation safety training and experience (e.g. format (lecture, online, etc.), and please provide provider of training in the five radiation safety topics outlined above.

- hands-on use of radioactive materials

The amount of training and experience needed will depend upon the type, form, quantity, and proposed use of the licensed material requested, but it should cover the subjects stated.

- (3) Please provide quantities of germanium-69 in oil with which each proposed AU has had hands-on experience, at the licensee's facilities. Include dates on which such experience was obtained, as available. For any additional hands-on experience, please provide date(s), institution(s) & location(s) where the proposed AUs had hands-on experience, applicable to uses requested under the license. Include isotopes and quantities.

An AU is supervising the use of radioactive materials when he or she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he or she is responsible for the safe use of radioactive material to ensure that areas are not contaminated.

Applicants must name at least one individual who is qualified to use the requested licensed materials. In general, AUs must demonstrate training and experience with the type and quantity of material they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

Response from Applicant:

Applicants should provide the following:

- name of each proposed AU with the types and quantities of licensed material to be used
- information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials; information should include, as a minimum:
 - formal training or education in radiation safety [topics covered; duration of training; when training was received; identity and location of training provider (note: a course outline may be provided)]
 - experience using licensed materials (types; forms; quantities handled; activities performed; duration of experience)

Applicants should provide information about the proposed AU's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

Request for information, continued, p.11 of 11

Forster, Sara

From: Forster, Sara
Sent: Friday, May 31, 2019 12:16 PM
To: mark.gomez@roush.com
Subject: Additional Information Request re Roush Industries, Inc. new license application, CN611716
Attachments: 03620.611716 RFAI via NRC 699 signed.pdf

Dear Mr. Gomez:

We have reviewed your March 12, 2019 application (NRC Accession No. ML19084A258) requesting a new radioactive materials license for the use of tetra-alkylated germanium-69 in oil.

Upon review, we have noted that the application omits information requested in the NRC's NUREG 1556 Vol. 7, rev. 1, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," guidance volume. We have also noted that the required fees (per Title 10 of the Code of Federal Regulations Section 170.31) and Taxpayer Identification Numbers (as noted on NRC Form 531) have not been received in full. I have attempted to call you on May 30, 2019, but received no response, to date. If I have not heard from you sooner, I will call you again with the next 1 to 10 business days to follow up with this request. As we may discuss further, please see attached for information needed to complete our review of your request.

To facilitate our continued review of your request, please provide additional information – via a signed and dated cover letter and resubmitted supporting information - as noted in the attached record.

Please provide the requested information within 14 days of this message (on or before June 14, 2019). Include a signed and dated cover letter transmitting your response. Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. If you wish to withdraw your application – without prejudice for resubmission – you may also do that. In the meantime, if you could please confirm receipt of this message, it is appreciated. Thank you for your prompt attention to this matter.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
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