



Rulemaking: Regulatory Framework for Fusion Systems

NRC Public Meeting
November 1, 2023

Agenda

Time	Topic	Speaker
1:00 pm	Welcome & Meeting Logistics	Dennis Andrukat
	Opening Remarks	Theresa Clark
	NRC Presentation – Overview of Preliminary Draft Guidance (NUREG-1556, Volume 22)	Duncan White Diego Saenz, WI
2:00 pm	BREAK	All
2:10 pm	Questions & Answer Session / Public Feedback	All
3:50 pm	Closing Remarks & Adjourn	Dennis Andrukat

Topic times are estimated and, depending on the participation level, the meeting could adjourn earlier than scheduled. If there are concerns with a potential early meeting adjournment, please inform the point of contact for this meeting.

Opening Remarks

Theresa Clark, Acting Director
Division of Operating Reactor Safety
Region IV
US NRC





Overview of Preliminary Draft Guidance

Duncan White

Division of Materials Safety, Security, State, and Tribal Programs

Office of Nuclear Material Safety and Safeguards

US NRC



Commission Direction

Fusion Systems

On April 13, 2023, the Commission issued SRM-SECY-23-0001 “Options for Licensing and Regulating Fusion Energy Systems” (ML23103A449) directing the staff to implement a byproduct material approach to fusion energy system regulation.



BYPRODUCT MATERIAL
FRAMEWORK



NUREG-1556 GUIDANCE

Overview of Licensing Byproduct Materials under 10 CFR 30

1

Limit access and use of radioactive material

2

Permit use of radioactive material by qualified individual

3

Assure adequate level of safety and security

4

Provide flexibility

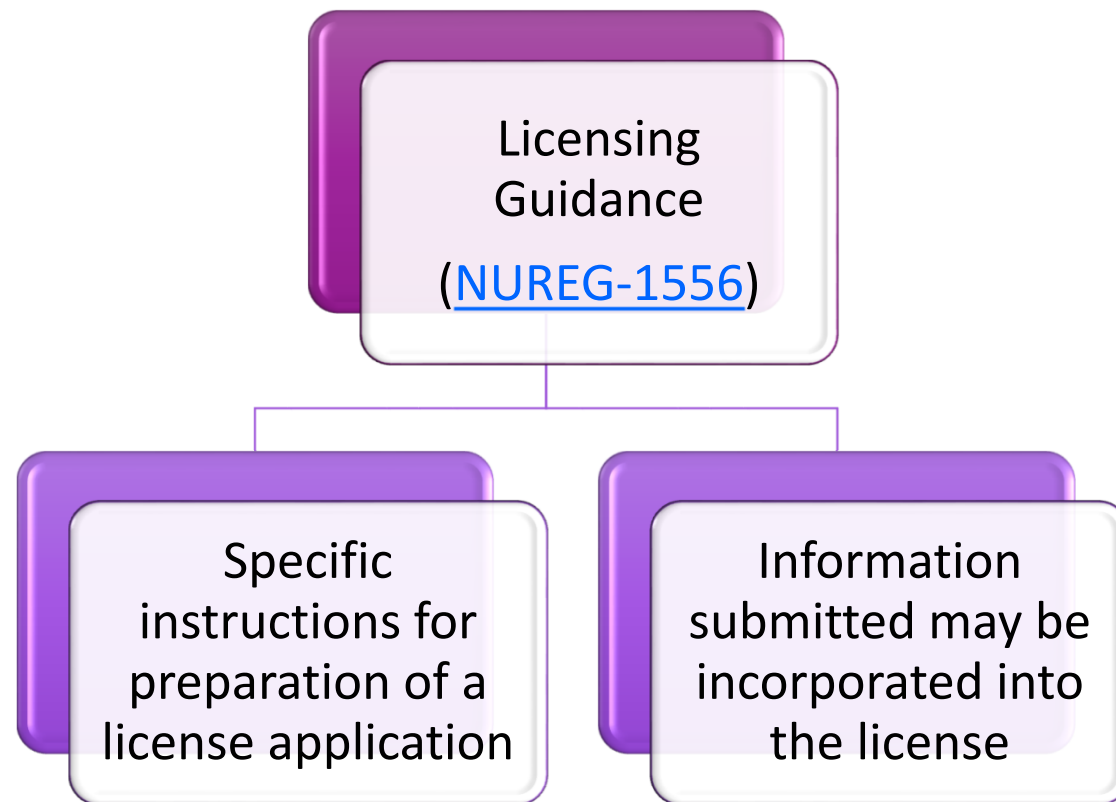
5

Impose reasonable restrictions

Overview of Licensing Byproduct Materials under 10 CFR 30

- Pre-Application Meetings
- Application Submittal
- Acceptance (administrative) review
- Technical Reviewer Assigned
 - Based on complexity
 - Training for less experienced reviewer
- Evaluation of Application
 - Compare to appropriate guidance
 - Review all aspects of the radiation safety program
 - Applicant required to provide response to identified deficiencies
- Pre-Licensing Visit
- License Issuance

Overview of Licensing Byproduct Materials under 10 CFR 30



Overview of Licensing Byproduct Materials under 10 CFR 30

Regulatory Guides

Address specific health physics or implementation issues (Division 8)

Additional NUREGs addressing specific topics

- NUREG-1757 for decommissioning funding plan and financial assurance
- NUREG-2155 and 2166 for security
- NUREG-1575 for MARSSIM (decommissioning of land and buildings)
- NUREG-1748 for environmental review guidance

Agreement State Programs

Assumption of Regulatory Authority

- NRC discontinues and Agreement State assumes regulatory authority.
- Not a delegated program.
- 88% of Specific Licenses are under Agreement State purview.

Compatible Program

- Compatible regulations, procedures, and guidance.
- Cohesive national program.

Agreement State Oversight

- Integrated Materials Performance Evaluation Program (IMPEP)
- Regulation Reviews



Wisconsin Agreement State Approach to Materials Licensing

Fusion Licensing Guidance Development

- NUREG-1556, Volume 22
- Cover contents of application and licensing process
- Intended to apply to fusion systems during research and development or commercial deployment
- Focus on byproduct material and associated radiation
 - Emphasis on containing, processing, or controlling radiation and radioactive materials.
 - Limited to specific components – not facility wide
- Additional changes to the preliminary draft guidance may be identified during the rulemaking process

NUREG-
1556
Volume 22

Table of Contents

ABSTRACT

FOREWORD

LIST OF FIGURES

LIST OF TABLES

ACKNOWLEDGMENTS

ABBREVIATIONS

1 PURPOSE OF REPORT

2 AGREEMENT STATES

3 MANAGEMENT RESPONSIBILITY

4 APPLICABLE REGULATIONS

5 HOW TO FILE

6 IDENTIFYING AND PROTECTING SENSITIVE
INFORMATION

7 APPLICATION AND LICENSE FEES

8 CONTENTS OF AN APPLICATION

9 LICENSE AMENDMENTS AND RENEWALS

10 APPLICATIONS FOR EXEMPTIONS

11 TERMINATION OF ACTIVITIES

APPENDICES

NUREG-1556 Guidance Standard Format

Regulatory Requirements

- Specific applicable regulations

Criteria

- Overall purpose of the section

Discussion

- Detailed areas and information needed on the topic
 - Information needed and details specific to applicant's design to demonstrate compliance with safety requirements
 - Information needed to ensure radiation protection
 - Information on applicant's hazard analysis (if required)

Response from Applicant

- Specific information needed in the response from applicant that will be used as commitment(s) in the license
- Based on information covered in Discussion section

Reference(s)

- Specific applicable agency document(s)




Contents of An Application – Form 313

- Item 1: License Action Type
- Item 2: Name and Mailing Address of Applicant
- Item 3: Address(es) Where Licensed Material Will Be Used or Possessed
- Item 4: Person To Be Contacted about This Application
- Item 5: Radioactive Material
- Item 6: Purpose(s) for Which Licensed Material Will Be Used
- Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience
- Item 8: Training for Individuals Working in or Frequenting Restricted Areas
- Item 9: Facilities and Equipment
- Item 10: Radiation Protection Program
- Item 11: Waste Management
- Item 12: License Fees
- Item 13: Certification

Contents of An Application

Items 1 – 4 and 12 – 13

NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION 10 CFR 30.32, 33, 34, 35, 36, 37, 39, and 40  APPLICATION FOR MATERIALS LICENSE		APPROVED BY OMB: NO. 3150-0120 Estimated burden per response is 30 minutes with the mandatory collection request. 4.3 hours. Submitting the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (7-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to infocollections.Resource@nrc.gov , and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: omb_31500120@omb.eop.gov . The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.	EXPIRES: 07/31/2026
INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1568 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reactors/nrc/doc-collections/nureg-staff-tr-1568 . SEND ONE COPY OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.			
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: MATERIALS SAFETY AND TRIBAL LIAISON BRANCH DIVISION OF MATERIALS SAFETY, SECURITY, STATE AND TRIBAL PROGRAMS OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001		IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH DIVISION OF RADIOLOGICAL SAFETY AND SECURITY U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352 REGIII.MAL.Resource@nrc.gov *Note: The preferred method to submit NRC Form 313 is email. Any other document (e.g., financial assurance documents) should be sent via mail.	
ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF RADIOLOGICAL SAFETY AND SECURITY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD, SUITE 102 KING OF PRUSSIA, PA 19406-1415 REGI.MAL.Resource@nrc.gov *Note: The preferred method to submit NRC Form 313 is email. Any other document (e.g., financial assurance documents) should be sent via mail.		IF YOU ARE LOCATED IN: ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH DIVISION OF RADIOLOGICAL SAFETY AND SECURITY U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAHAR BOULEVARD ARLINGTON, TX 76011-4511 REGIV.MAL.Resource@nrc.gov *Note: The preferred method to submit NRC Form 313 is email. Any other document (e.g., financial assurance documents) should be sent via mail.	
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.			
1. THIS IS AN APPLICATION FOR (Check appropriate item) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____		2. NAME AND MAILING ADDRESS OF APPLICANT (include zip code) _____ _____ _____	
3. LIST ADDRESS AND/OR TEMPORARY JOB SITE (TJS) ADDRESS, WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED _____ _____ _____		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION _____ BUSINESS TELEPHONE NUMBER _____ BUSINESS CELLULAR TELEPHONE NUMBER _____ BUSINESS E-MAIL ADDRESS _____	
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE APPLICABLE LICENSING GUIDANCE.			
5. RADIOACTIVE MATERIAL. a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.		6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.	
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.		7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	
10. RADIATION SAFETY PROGRAM.		9. FACILITIES AND EQUIPMENT.	
12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.3f) *Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.		FEE CATEGORY _____	AMOUNT ENCLOSED \$ _____
PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 631: http://www.nrc.gov/reactors/nrc/doc-collections/forms/trs631info.html. FAX THE COMPLETED NRC FORM 631 TO (801) 416-8726.			
13. CERTIFICATION: (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 3, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30.32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 52 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.			
CERTIFYING OFFICER - TYPE/PRINTED NAME AND TITLE _____		SIGNATURE _____	DATE _____
FOR NRC USE ONLY			
TYPE OF FEE _____	FEE LOG _____	FEE CATEGORY _____	AMOUNT RECEIVED _____
APPROVED BY _____	DATE _____	CHECK NUMBER _____	COMMENTS _____

Contents of An Application Items 5 & 6

Radioactive Material

Unsealed:

- Provide an element name with mass number, chemical and/or physical form, and a maximum requested possession limit for each radionuclide produced.
- Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored, and waste materials.
- Fusion: Tritium

Sealed or Solid:

- Identify each radionuclide (element name and mass number) or groups of radionuclides (activation products)
- If a sealed source, provide the manufacturer or distributor's name, model number for each sealed source, device, or source/device combination requested, and maximum activity listed on the approved certificate of registration issued by NRC or Agreement State.
- Fusion: Tritium and Activation products in fusion system components, shielding and waste. Radioactive sources used for calibration of survey and laboratory equipment

Purpose(s) For Which Licensed Material Will Be Used

List the specific use or purpose of each unsealed or sealed/solid radionuclide

Contents of An Application Items 5 & 6

Sample Format for Providing Information About Requested Radionuclides

Byproduct Material Radionuclide	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Hydrogen 3	Any	____ Ci [____gm]	Fuel for fusion system and production and possession
Activation Product	Any	____ Ci	Possession and storage incident to fusion and production activities
Cesium 137	Sealed Source (insert manufacture and model number)	Not to exceed ____ mCi per source and ____ mCi total	Calibration and check of instruments

Contents of An Application Items 5 & 6

Financial Assurance and Recordkeeping for Decommissioning



Licensee possession limits exceeding those specified in 10 CFR 30.35 must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning.



Licensees are required under 10 CFR 30.35(g) to maintain records important to decommissioning



Submit evidence of financial assurance following the guidance of NUREG-1757, Volume 3

Contents of An Application Item 7

Individual(s) Responsible for Radiation Safety Program and Their Training and Experience



OUTLINES TYPICAL DUTIES AND RESPONSIBILITIES



DESCRIBES MINIMUM REQUIREMENTS FOR TRAINING AND EXPERIENCE (T&E)



STRUCTURED AFTER ACADEMIC AND R&D LICENSING GUIDANCE

Contents of An Application Item 7

Radiation Safety Officer (RSO)

Named on the license

Responsible for the radiation protection program

Independent authority to stop unsafe operations

Must have adequate training

- Understand hazards of radioactive material used by licensee
- Familiar with applicable regulatory requirements

Contents of An Application Item 7

Individuals Authorized to Handle Radioactive Material

Training and experience (T&E) reviewed by NRC or Agreement State

Either named individuals or approved training program to handle radioactive material

Primary responsibility to ensure radioactive material is used safely and in accordance with regulatory requirements

Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.

Contents of An Application Item 8

Training for Individuals Working in or Frequenting Restricted Areas

Individuals whose assigned duties involve exposure to radiation or radioactive material and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 millisievert (mSv) [100 millirem (mrem)], must receive instruction commensurate with scope of those duties.

Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.

Contents of An Application Item 9

Facilities and Equipment	General Description of Facility and Site
	Access Control
	Shielding
	Fire Protection
	Radiation Monitors
	Tritium Handling System
	Breeding Blankets
	Heat Removal
	Power Failures

Contents of An Application Item 10

Radiation Protection Program

Audit Program

Radiation Monitoring Instruments

Material Control and Accountability

Activation Products

Tritium Production

Occupational Dose

Tritium Bioassay Program

Public Dose

Operating Procedures

Emergency Procedures

Surveys and Leak Tests

Contents of An Application Item 10

Radiation Protection Program

Maintenance

Transportation

Minimization of Contamination

Evaluation for need of Emergency
Preparedness Plan

Accident Scenarios

Offsite Doses from Accident Scenarios

Effluent Monitoring

Environmental Surveillance

Security

Material Control & Accountability



For unsealed licensed material, various methods (e.g., computer programs, manual ledgers, logbooks) may be used to account for production, use, transfer, disposal, and radioactive decay.



A tool for tritium inventory evaluation within each sub-system of the fuel cycle is necessary.



Accountability procedures

Material Control & Accountability

10 CFR 30.55 Tritium Reports

Each licensee who is authorized to possess tritium shall report any incident in which an attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or more than 100 curies of such material in any one calendar year.

Emergency Procedures

- Must have and follow emergency or abnormal event procedures
 - Include event reporting
- Establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by emergency personnel.
 - Spills or releases of radioactive material
 - Safety related equipment malfunctions
 - Overexposures
- Clearly identify contact information for RSO or other individuals who can assist
- Different from the requirement to evaluate offsite consequences for an emergency plan - focus is on on-site response by licensee

Contents of An Application Item 11

Waste Management

- Discuss the methods for management and storage and ultimate disposal of radioactive waste (tritium, contaminated equipment, activated components).
 - Transfer to a low-level radioactive waste disposal facility
 - Decay-in-storage (half-life < 120 days)
 - Effluent releases under 10 CFR 20.1302(b)(2)
- The program should include procedures for waste minimization, waste characterization, waste handling, safe and secure storage, and waste disposal.



A photograph of two blue ceramic coffee cups filled with latte, each with intricate latte art. The cups are set on matching blue saucers and are placed on a rustic wooden table. The word "Break" is overlaid in white text on the coffee in the foreground cup.

Break

A purple-tinted background image showing a group of people in a meeting or conference. Several individuals have their hands raised, indicating an interactive session. The image is overlaid with a white horizontal line near the top and white text.

+ • Question & Answer Session

Please Note: the NRC is not accepting official comments during this meeting and will not provide any official responses to any feedback provided during this meeting.

Upcoming Events/Milestones

Upcoming Public Meeting

- November 9, 2023 - Specific Topics
- Additional meeting(s) – to be determined

Proposed Rule Schedule

- Proposed rule and draft guidance to Commission by Fall 2024

Thank You!

Contacts

Dennis Andrukat, *Rulemaking Project Manager*

Dennis.Andrukat@nrc.gov

Duncan White, *Technical Lead*

Duncan.White@nrc.gov

Presentation: ADAMS Accession No. ML23258A171

Handout: ADAMS Accession No. ML23258A172

Public Information

NRC Public Website:

<https://www.nrc.gov/materials/fusion-energy-systems.html>

Docket ID: NRC-2023-0071
(www.regulations.gov)

Meeting Notice / Feedback Form:

<https://www.nrc.gov/pmns/mtg?do=details&Code=20231013>