

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, DC 20555-0001

January 10, 2014

**NRC REGULATORY ISSUE SUMMARY 2014-01
REGULATORY REQUIREMENTS FOR WITHHOLDING OF
PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE**

ADDRESSEES

All distributors of general license devices submitting a request that information be withheld from public disclosure under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.390, "Public Inspections, Exemptions, Requests for Withholding."

INTENT

The U.S. Nuclear Regulatory Commission (NRC or Commission) is issuing this regulatory issue summary (RIS) to inform addressees how to request withholding of proprietary information from public disclosure under 10 CFR 2.390(b) and how to submit proprietary information to the NRC. This RIS does not transmit any new requirements or new staff positions. No specific action or written response is required. The NRC is providing this RIS to the Agreement States for their information and for distribution, as appropriate, to their distributors of general licensed devices.

BACKGROUND

Over the last year, NRC staff has received requests for withholding of proprietary information that do not state a basis or comply with the conditions for withholding in 10 CFR 2.390. This resulted in NRC discussions and correspondence with the licensees to obtain revised 10 CFR 2.390 submittals, resulting in delays and additional expenditure of resources.

The regulation in 10 CFR 2.390(b)(1) states that the submitter shall request withholding at the time the document is submitted and shall comply with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

As discussed in Information Notice 2009-07, "Withholding of Proprietary Information from Public Disclosure," 10 CFR 2.390(b)(2) states that a person who submits commercial or financial information believed to be privileged or confidential or a trade secret shall be on notice that it is the policy of the Commission to achieve an effective balance between legitimate concerns for protection of competitive positions and the right of the public to be fully apprised as to the basis for and effects of licensing or rulemaking actions, and that it is within the discretion of the Commission to withhold such information from public disclosure. The NRC is required by 10

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CFR 2.390(b)(3) to determine whether information sought to be withheld from public disclosure is a trade secret or confidential or privileged commercial or financial information and, if so, whether it should be withheld. The NRC staff reviews all proprietary submittals to ensure that the basis for withholding is supportable in accordance with 10 CFR 2.390(b)(4) and that submittals comply with the affidavit and marking requirements in 10 CFR 2.390(b)(1). The NRC staff must then, pursuant to 10 CFR 2.390(b)(5), determine: (1) whether the right of the public to be fully apprised of the proposed action outweighs the demonstrated concern for protection of a competitive position, and (2) whether the information should be withheld.

SUMMARY OF ISSUE

To ensure future submittals comply with the requirements in 10 CFR 2.390, the NRC staff communicates the following:

1. Each submittal requesting withholding of proprietary information from public disclosure must include an affidavit unless the submittal is requesting withholding of personal privacy information or the NRC has waived the affidavit requirement. Unless one of these exceptions apply the affidavit must –
 - a. Be submitted at the same time as the request for withholding, which must be submitted at the time that the document containing information sought to be withheld is submitted.
 - b. Identify the document or part sought to be withheld.
 - c. Identify the official position of the person making the affidavit. If the affidavit has been submitted by a company, the person executing the affidavit shall be an officer or upper-level management official who has been specifically delegated the function of reviewing the information sought to be withheld and authorized to apply for its withholding on behalf of the company. Furthermore, the affidavit shall be executed by the owner of the information, even if the information is submitted to the Commission by another person.
 - d. Declare the basis for proposing the information be withheld, consistent with the considerations set forth in 10 CFR 2.390(a).
 - e. Contain a specific statement of the harm that would result if the information sought to be withheld is disclosed to the public.
 - f. Indicate the location(s) in the document of all information sought to be withheld.
 - g. Contain a full statement of the reason for claiming the information should be withheld from public disclosure. The statement must address, with specificity, the considerations listed in 10 CFR 2.390(b)(4).

2. Information sought to be withheld must be marked appropriately. 10 CFR 2.390(b)(1)(i) requires that the submitter ensure that the document containing information sought to be withheld is marked as specified in 10 CFR 2.390(b)(1)(i)(A) and (B). The NRC Staff recommends marking the top of the first page of the document and the top of each page containing such information as “proprietary” to indicate it contains information the submitter seeks to have withheld; however, the staff notes that 10 CFR 2.390(b)(1)(i)(A) permits other styles of marking, such as the use of electronic watermark. In addition, the document containing information sought to be withheld must indicate, adjacent to the information, or in the manner authorized in 10 CFR 2.390(b)(1)(i)(A) if the entire page is affected, the basis for proposing that the information be withheld from public disclosure.

As discussed in RIS 2004-11, “Supporting Information Associated with Requests for Withholding Proprietary Information,” some examples of reasons for withholding documents are the following:

1. The information requested to be withheld reveals the distinguishing aspects of a process (or component, structure, tool, method, etc.) whose use by any of the submitter’s competitors, without a license from the submitter, would constitute a competitive economic disadvantage to the submitter.
2. The information requested to be withheld consists of supporting data, including test data, relative to a process (or component, structure, tool, method, etc.), and the application of the data secures a competitive economic advantage, as described more fully in the affidavit.
3. Use by a competitor of the information requested to be withheld would reduce the competitor’s expenditure of resources, or improve its competitive position, in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.
4. The information requested to be withheld reveals cost or price information, production capacities, budget levels, or commercial strategies of the submitter or customers or suppliers.
5. The information requested to be withheld reveals aspects of privately funded development plans or programs of commercial value to the submitter or owner of the information.
6. The information requested to be withheld consists of patentable ideas.

Although submitters are not required to do so, the NRC staff encourages submitters to provide a nonproprietary version, suitable for public disclosure, having brackets around the information that was deleted from the proprietary version. This voluntary measure would allow the NRC staff to efficiently and effectively respond to requests for release of the submitter’s information (e.g., Freedom of Information Act requests). However, for instances in which a nonproprietary version would be of no value to the public because of the amount of proprietary information included in the document, the agency does not encourage submittal of a nonproprietary version.

BACKFIT DISCUSSION

This RIS requires no action or written response beyond that already required by the regulations; therefore, there is no backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808).

RELATED GENERIC COMMUNICATIONS

1. Regulatory Issue Summary 2004-11, "Supporting Information Associated with Requests for Withholding Proprietary Information," Agencywide Documents Access and Management System (ADAMS) Accession No. ML041180231.
2. Information Notice 2009-07, "Withholding of Proprietary Information from Public Disclosure," ADAMS Accession No. ML082460249.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain information collection requirements and, therefore, is not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

CONTACT

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the technical contact listed below or the appropriate regional office.

/RA/

Laura A. Dudes, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contact: Hector Rodriguez-Luccioni, MSSA/FSME
(301) 415-6004
E-mail: Hector.Rodriguez-Luccioni@nrc.gov

Enclosure:
List of Recently Issued FSME
Generic Communications

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OFC	FSME/MSSA/LB	FSME/MSSA/LB	FSME/MSSA/RMSB	OE	OIS
NAME	HRodriguez-Luccioni	MKotzalas	GRivera-Capella for AMcIntosh	NHilton	TDonnell
DATE	12/17/2013	12/18/2013	12/19/2013	12/30/2013	12/27/2013
OFC	OGC-NLO and CRA	FSME/MSSA			
NAME	MAAlbert	LDudes			
DATE	1/2/2014	1/10/2014			

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List of Recently Issued Office of Federal and State Materials and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
11/15/2013	IN-2013-22	Recent Licensing Submittals Containing Personally Identifiable Information	All materials licensees, certificate holders, applicants, and other entities subject to regulation by the U.S. Nuclear Regulatory Commission for the use of source, byproduct, and special nuclear material. All Radiation Control Program Directors and State Liaison Officers.
10/17/2013	RIS-2013-17	Resuming Normal Interactions Between the NRC and NRC Stakeholders Following an Agency Shutdown	All U.S. Nuclear Regulatory Commission (NRC) licensees, certificate holders, permit holders, and applicants; all Agreement and Non-Agreement States, and State Liaison Officers; and other interested stakeholders.
10/09/2013	RIS-2013-16, Supp. 1	Interactions Between the NRC and NRC Stakeholders During a Lapse of Agency Appropriations	All U.S. Nuclear Regulatory Commission (NRC) licensees, certificate holders, permit holders, and applicants; all Agreement and Non-Agreement States, and State Liaison Officers; and other interested stakeholders.
10/01/2013	RIS-2013-16	Interactions Between the NRC and NRC Stakeholders During a Lapse of Agency Appropriations	All U.S. Nuclear Regulatory Commission (NRC) licensees, certificate holders, permit holders, and applicants; all Agreement and Non-Agreement States, and State Liaison Officers; and other interested stakeholders.
09/16/2013	IA-03-02	Criteria for Reporting Cybersecurity Incidents	All Radiation Control Program Directors and State Liaison Officers. All Increased Controls (IC) materials licensees. All licensees possessing Category 2 and higher materials.

List of Recently Issued Office of Federal and State Materials and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
09/11/2013	RIS-2013-14	Reporting Transactions Involving Temporary Jobsites to the National Source Tracking System	All industrial radiography and well logging licensees, and all Radiation Control Program Directors and State Liaison Officers
<p>Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs. A full listing of all generic communications may be viewed at the NRC public Web site at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</p>			