

From: Ujagar Bhachu
To: "carterd@ipa.net"@GATED.nrcsmtp
Date: Wed, Jan 5, 2000 1:32 PM
Subject: Re: Discussion of Inactivating Registration Certificate.

Attached for your information and use is Section 13 of the NUREG 1556 Vol. 3, "CONSOLIDATED GUIDANCE ABOUT MATERIAL LICENSES." Required information for inactivation of a registration certificate is indicated in Section 13.4.

If you have any further questions please call me on 301-415-7894.

For guidance on termination of your licenses please contact Arkansas Department Of Health, Division of Radiation Control and Emergency Management. (501) 661-2301) You may wish to inform the Arkansas Radiation Authority that you are in the process of requesting NRC to inactivate your Registration Certificate Number AR-0101-D-10-G.

Ujagar S. Bhachu

>>> Darrell Carter <carterd@ipa.net> 01/05 12:40 PM >>>
U.S. Bhachu:

Thank you for the call and for the information that you will be sending. We hope to get our license to an inactive status quickly and I will be forwarding the proper information to you within a few days.

Thank you,

Darrell Carter
General Manager
STI
Waldron, Arkansas 72958

CC: Frederick Sturz, Linda McLean

PDR RC * SSD

13 Modifications to Existing Registration Certificates

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It is the obligation of the registration certificate holder to keep the registration certificate current. If a registration certificate holder plans to make a change to the registered product that affects the commitments made in the information provided in support of the application or the conditions included in the registration certificate, the registration certificate holder must file for an amendment or correction to the registration certificate. Until the amendment request is approved and the amended certificate is issued, the registration certificate holder is obliged to comply with the information in the certificate. Registration certificate holders are encouraged to anticipate the need for certificate amendments as far in advance as possible.

An application to amend a certificate should be prepared in triplicate. The registration certificate holder should retain one copy for their records and submit the original and one additional copy to the address specified in Section 7. The application should identify the registration certificate by number and should clearly describe the changes and the effects of the changes on the safety properties of the product. References to previously submitted information should be clear and specific and should identify that information by date, document title, and page number.

An application to amend a certificate should be accompanied by the appropriate fee (Section 8) and, for medical products, the registration certificate holder needs to notify FDA about the proposed changes to the product.

The request for an amendment or correction needs to address the changes to the product and how the changes affect the original safety evaluation of the product. The reviewer needs to evaluate the changes to determine if they have any adverse effects on the safety of the product and whether the initial evaluation and the determination of adequacy are still valid. The reviewer needs to look at all aspects of the initial evaluation to determine if the change would have an

effect on another aspect of the evaluation that may not be readily evident. For example, changing a part of the source holder from stainless steel to lead may improve the shielding efficiency, but may have detrimental effects on how the device will react to accident conditions. This type of detrimental effect may have been overlooked by the manufacturer.

13.1 Amendments

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If the registration certificate holder requests an amendment to the certificate (i.e., it requires a safety evaluation to be performed), the certificate should be amended in its entirety. The certificate header should include, under the title, the following:

(AMENDED IN ITS ENTIRETY)

The certificate should be assigned a new issue date, and the certificate should be re-issued in its entirety. When appropriate, the reviewer should use bold type face and strike-out to highlight the changes that have been made to the certificate. In addition, if there are still products in use that meet the previous design specifications, reviewers must ensure that previous design information remains in the registration certificate. The registration certificate also must identify, by date or serial number, when the design change is implemented.

13.2 Corrections

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If the change only involves corrections to the certificate (i.e., does not require a safety evaluation to be performed such as change in address or error identified in the certificate), then only the affected pages of the certificate need to be updated and issued. The reviewer should use bold type face to make the corrections. Each affected page should include, in the header, under the title, the words "CORRECTED PAGES," the number of each page affected, and the date of the correction. An example of this format is shown below:

(CORRECTED PAGES 1, 2, & 4 - JULY 5, 1776)

The issue date of the certificate should remain the same as the last issue date. It is not necessary to include the letter from the registration certificate holder in the reference section of the certificate.

If the correction requires a change to the signature page of the certificate, the certificate should be amended in its entirety. The reviewer may elect to hold off making corrections to the signature page until the registration certificate holder requests an amendment, requiring a safety evaluation, to the certificate.

13.3 Combining Registration Certificates

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Registration certificate holders may request that NRC combine two or more certificates into a single certificate. However, it is IMNS policy that only products which are essentially identical in design, function, construction, and which vary only in a dimensional capacity, in the sources used or in their application, may be grouped together on a single registration certificate.

Combining registration certificates does not require a safety evaluation. However, the reviewer must determine whether the request meets IMNS policy and can administratively combine the registration certificates.

13.4 Transfers to Inactive Status

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If a registration certificate holder requests that a registration certificate be transferred to inactive status⁽¹⁾, the registration certificate holder should provide:

- the total number of the products sold; the number of products still in use⁽²⁾;
- the services (including source replacement and availability) the registration certificate holder will still provide to users of the product or the identification of an entity that will provide services;
- a commitment that the registration certificate holder will no longer commercially distribute the product; and,

- verification that no changes were made to the product since its initial registration or last amendment.

The reviewer must verify that the above information is included and that the background file for the product evaluation is complete and accurate. Because some registrations were issued many years ago, the files may not include all the information that is now required. Therefore, the reviewer should request that the registration certificate holder submit any and all additional information that would be needed to make a determination that the product is acceptable for licensing purposes. The reviewer needs to write an updated registration certificate, including the new registration number (see Appendix J for issuance of inactive registration certificate numbers) and updated information. The new certificate will contain a statement that the product will no longer be commercially distributed but may still be approved for licensing purposes. The registration certificate will replace the old registration certificate and will be used as the basis for continued licensing of the product.

13.5 Re-activating Inactive Registration Certificates

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Vendors may submit requests to re-activate inactive registration certificates. Requests to re-activate inactive registration certificates are handled in one of the two methods:

1. If the background information on file with the NRC for the inactive registration certificate is complete, up-to-date, and the vendor does not request any changes to the information, the vendor may simply submit a letter to the NRC requesting re-activation of the registration certificate. The letter must include commitments that the information on file with the NRC is complete and accurate and that the vendor commits to abide by all information on file with the NRC. The reviewer must verify the information is complete prior to assigning a new registration certificate number and re-issuing the certificate
 2. If the background information on file with the NRC for the inactive registration certificate is incomplete, not up-to-date, or the vendor requests changes to the information (e.g., changes in the design of the product or manufacturing or distribution procedures), the vendor must submit a complete application for evaluation and registration in accordance with this document. The reviewer must review and evaluate the application in the same manner as a new application.
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1. NRC also will transfer a registration certificate to inactive status if it knows the registration certificate holder is out of business.
2. The actual number of products sold and still in use may not be known by the registration certificate holder. The registration certificate holder however, should still provide a best estimate.

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to the Chief, Sealed Source Safety Section, OWFN Mail Stop O-6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER John Hoyle		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> HQ <input type="checkbox"/> LFARB			
TELEPHONE NUMBER	DATE	TYPE OF ACTION REQUESTED (Check as appropriate)			
NAME OF APPLICANT		<input type="checkbox"/> SOURCE REVIEW	<input type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S)		
MAIL CONTROL NUMBER(S)		<input checked="" type="checkbox"/> DEVICE REVIEW	AR-101-D-101-G		
LETTER/APPLICATION DATE	LICENSE NUMBER(S)	<input type="checkbox"/> CUSTOM REVIEW			

COMMENTS:
Staff Requirements Memo - SECY-98-215

FOR SSSS USE ONLY

REVIEWER Ujagar Bhachu	MODEL NUMBERS 4000	NUMBER ASSIGNED 99-35
DATE RECEIVED 05/12/1999	DATE ASSIGNED 05/12/1999	DATE TO FEES 05/12/1999

TYPE OF ACTION (Indicate the number of each type)

<input type="checkbox"/> COMMERCIAL DISTRIBUTION (FORMAL)		<input type="checkbox"/> USE BY A SINGLE APPLICANT (CUSTOM)	
SOURCE (9C)	SOURCE (9A)	SOURCE (9D)	SOURCE (9B)
<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT
<input checked="" type="checkbox"/> NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED (IF KNOWN)	<input type="checkbox"/> YES <input type="checkbox"/> NO

OTHER (Specify)

TOTAL NUMBER OF REVIEW HOURS	NOTES Reviewer to review for compliance with NRC regulations.
NUMBER OF DEFICIENCY LETTERS	
NUMBER OF DEFICIENCY CALLS	

FOR FEE USE ONLY

TYPE OF FEE	FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D			
AMOUNT RECEIVED	CHECK NUMBER	DATE OF CHECK	LOG	
APPROVED BY				DATE OF RETURN
COMMENTS				