

From: John Nicholson
To: AVancha@yahoo.com; E_meadow@yahoo.com
Date: Tue, Mar 1, 2005 2:18 PM
Subject: new license application Mail Control # 136340

Gentlemen:

In your application you committed to establishing and implementing many of the Model Procedures published in NRC Regulatory Guide 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs." This guide was published in August 1987 and was designed for use with the NRC's medical regulations that existed in 10 CFR Part 35 at that time. On April 24, 2002, NRC published new medical regulations in 10 CFR Part 35. These regulations became effective on October 24, 2002. Concurrent with the issuance of the new medical regulations, NRC published NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" (Enclosure 2). As specified in Appendix AA of NUREG-1556, Volume 9, Regulatory Guide 10.8, Revision 2 is superceded and should no longer be used.

Please use NUREG-1556, Volume 9, in preparing your license application. You will note that new Part 35 and this guidance generally do not require the submission of detailed procedures during the licensing process. As detailed in NUREG-1556, Vol. 9, in many cases a licensee is required only to supply a statement regarding the development, implementation, and maintenance of written operating and emergency procedures. Section 8 Contents of an Application and Appendix C of NUREG-1556, Volume 9, should be helpful in identifying the information required by NRC to process your request for license renewal.

For each item in Section 8 there is a "Response from Applicant" section that describes what information must be provided. Following this guidance closely will ensure a more timely approval of your new license application. Please contact me at 610-337-5236 if you have any questions while drafting your new application. No additional fee is required. Refer to Mail Control number 136340 with any additional information you submit regarding this action.

Mr. Anthony you stated you thought it would be possible to have a new application completed and mailed in to our office by Monday March 7, 2005. Please let me know if you will not be able to submit the new application by that time.

The link to NUREG-1556, Volume 9 is:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/>

Regards,

John Nicholson

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Subject: new license application Mail Control # 136340
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From: John Nicholson

Created By: JJN@nrc.gov

Recipients

yahoo.com

AVancha (AVancha@yahoo.com)

E_meadow (E_meadow@yahoo.com)

Post Office**Route**

yahoo.com

Files

MESSAGE

Size

3864

Date & Time

Tuesday, March 1, 2005 2:18 PM

Options

Expiration Date:

None

Priority:

Standard

Reply Requested:

No

Return Notification:

None

Concealed Subject:

No

Security:

Standard