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Date: 6/5/02 1:06PM
Subject: NRC RuleForum Form Submission: Review of Inspection Procedures/Manual for Broad Scope Medical and Diagnostic Medical Licensees

Who: Peter G. Vernig
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Re: Review of Inspection Procedures/Manual for Broad Scope Medical and Diagnostic Medical Licensees
Comments:

To:
U.S. Nuclear Regulatory Commission
Washington D.C.

From:
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DIVISION

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Subject: Comments on NRC Inspection Manual Inspection Procedure 87119 & 8710X, Medical Broad-Scope" and "Nuclear Medicine Programs that involve Diagnostic Applications"

Note it is presumed that many of the comments would also apply to Procedures 87115, "...Diagnostic and Therapeutic Applications" and 87118, Brachytherapy Programs

Unless otherwise noted page and paragraph designations refer to those in 87119, Broad Scope and generally will also apply to corresponding provisions in the other medical inspection procedures.

Page 3, 02.10 Management Oversight, refers to "audits for ALARA". ALARA is no longer defined in 10 CFR 35 and although a general requirement for materials licensees continues in 10 CFR 20.1101, there is no requirement for an ALARA audit and that reference to one, should be removed from this paragraph.

Page 3, 02.11 "other Uses of Byproduct Material...", The manual refers to "emerging technologies". If as the review feels is likely, this is referring to use under 35.1000, then emerging technologies is not the correct term to use and was identified in an NRC conducted workshop on medical licensing guidance held on April 25, 2002 as an incorrect and confusing term to use when referring to 10 CFR 35.1000. Specifically intravascular brachytherapy [IVB] is considered a use not covered under the other subparts and comes under subpart 35.1000 not because it is emerging, three devices have been approved by the FDA for IVB for routine treatment of restenosis, but because it is not covered appropriately under another subpart.

Page 3, 02.13, "Exit Meeting", negative Performance Evaluation Factors (PEFs) are cited and reference is made to IP 87101 that is not included. Evaluation of the appropriateness and regulatory support for PEFs should be part of this evaluation.

Page 5/6, 03.02, "Entrance Briefing", the last paragraph suggests observation of periodic tests and drills. If a test or drill was already scheduled to occur it certainly would be reasonable for NRC inspectors to observe it. However NRC should insure there is no implicit idea that the licensee should conduct such a drill for the NRC inspector to observe. Such a request would be disruptive and intrusive and should only

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be made if there is an indication of a serious problem or possible violation of regulations. That should be made clear in this section.

Page 9, 03.04, "Security and Control", I. "Posting and Labeling", Second paragraph says, "..., the inspector should verify that areas with radiation hazards have been conspicuously posted as required by 10 CFR 20.1902. Posting required by cited paragraphs refers to both posting of high and very high radiation areas, as well as radiation areas and radioactive materials areas. High and very high radiation areas may be considered radiation hazard areas radiation areas and radioactive materials are not radiation hazards. The word hazard should be removed or the section appropriately edited to indicate only high and very high radiation areas as hazards. Airborne radiation areas, also covered, may or may not be a hazard.

Page 9, 03.04, "Security and Control", J. "Inventories", Starts discussing the 10 CFR 35.67(g) requirement for semi-annual inventory of all sealed sources, then says "From those discussions, observations and reviews, if necessary, the inspector should physically examine the inventory of radioactive material on hand or examine records of receipt and transfer to determine that the quantities and forms are as authorized in the license." This is a confusing change from sealed source inventory to inventory of all radioactive materials. While all materials must be accounted for there is not a specific requirement to do a physical inventory of all radioactive materials present. The reviewer has had inexperienced NRC inspectors request quarterly inventories of all radioactive material. It is now apparent that the inspectors were not to blame but poorly worded inspection guidance was. Any discussion of examining material for compliance of the form and quantity of unsealed byproduct!

! t material should be separated from that of the semiannual inventory requirement for sealed sources.

Page 10, 03.04, "Security and Control", K. "Waste Storage and Disposal", First there are two paragraphs in the diagnostic procedure, 8710X that are not present in the Broad Scope procedure. The first seems appropriate, the second does not and should be omitted from the diagnostic and other procedures as appropriate. The second paragraph instructs the inspector to determine the Class of material. That is normally not done until till the material is being prepared immediately subsequent to shipment and will only waste both the inspector and licensees time. Second there should be a notation in the first paragraph that is currently in the Broad Scope procedure that the ten half-lives rule has been rescinded. That rule existed only in the old part 35 but many in the field have been indoctrinated with the ten half-lives rule. It would be well to inform the inspectors that material must be indistinguishable from background but need not have been held any specific length of time!

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Page 10, 03.04, "Security and Control", E. "Effluents", Fourth paragraph, "The inspector should review the licensee's ALARA goals, and determine if they are sufficiently challenging yet realistic."

Where is the regulatory requirement for ALARA goals for materials licensees? This paragraph should be omitted.

Page 12. 03.08 "Radiation Instrumentation...", A. "Equipment and Instrumentation", 1.a. "the radiation survey instruments have been calibrated in accordance with 10 CFR 35.61;" 10 CFR 61 (a) is quoted, in part, "A licensee shall calibrate the survey instruments used to show compliance with this part..." Since this section requires calibration in mrem/hr. And the standard instrument of the medical and most other materials licensees is the GM survey meter which is not appropriate for reading dose rate unless calibrated with radiation of the same type and close in energy to that which the dose or dose equivalent rate is being measured. And since the NRC since its inception has ignored those two situations and required such inappropriate calibration for most material licensees it should be pointed out to the inspection personnel that only a few or even a single instrument need be calibrated in this manner to show compliance and that many instruments may be calibrated as contaminated!

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ion survey meters, electronic linearity and either a source check or a determination of the efficiency for

isotopes of interest.

Page 13, 03.08 "Radiation Instrumentation...", A. "Area Radiation and Removable Contamination Surveys. First this should be letter "B" not "A". Second there are no removable contamination surveys required by 10 CFR 35, so that should be removed from the title.

Procedure 8710X, diagnostic, page 14, 03.09, "Radiation Safety Training...", B. "Operating and Emergency Procedures", B. Discuss with cognizant licensee representatives, or if practical, observe licensee personnel conduct periodic tests and drills, especially for scenarios involving fires and large releases of radioactive materials."

This is not in the Broad Scope procedure where it might make some sense. While a discussion of scenarios involving fire may be appropriate in a medical licensee with only diagnostic applications, those involving large releases of radioactive materials are not. Just how is a large release beyond the facility's boundaries expected to occur? Reference to large releases should be omitted.

Page 16, 03.10, "Management Oversight", F. "Financial Assurance...", The second paragraph refers to release of rooms for unrestricted use and suggests the inspector, "...perform confirmatory measurements to verify that radiation and contamination levels are below release limits." The implication is that the inspector should verify by measurements all the surveys for released rooms. It is the opinion of this reviewer that that section was written by someone who has not inspected a facility in the field in recent years, if ever. Even a medium sized broad scope licensee is likely to have had several rooms released in the interval between inspections. Larger broad scope licensees may have released many rooms.

An inspector might do abbreviated surveys in a couple rooms, collecting samples for later analysis but that will likely delay inspection reports. An inspector is in no position to verify surveys of several released rooms or areas within the constraints of the average materials inspection. It makes more sense for an inspector to question the technique of the licensee, perhaps have a demonstration and make a decision about whether to do spot checking and how much to do.

Page 20, 03.11, "Other Medical Uses of Byproduct ...", First there is a typo where it should say, "...a record of the RSC's review..." in the middle of the paragraph. Second reference is made to a safety evaluation made IAW 10 CFR 33 for new uses. It is suggested that the reference be made more specific, 10 CFR 33.[c](3)(ii) and (iii). Again throughout this paragraph the term new emerging technologies is used and reference is made to 35.1000. Emerging technologies is not used anywhere in 35.1000 and at least some of the references should probably be changed to "new uses not covered in other subparts of part 35".

Page 20, 03.12, "Independent and Confirmatory Measurements", "Examples of measurements that may be performed include area radiation surveys, wipe samples, leak tests, etc". Confirmatory measurements of dose rates may be done by inspection personnel but unless there is reason to be concerned verifying results of wipe tests and leak tests will increase the burden of inspectors considerably. Samples must be taken, packaged and preserved and then sent with paperwork to appropriate labs. It by all means should be done if there is an indication of a problem but do it routinely seem unrealistic. Again, it would seem to make more sense for inspectors to question technique, ask for demonstrations and base a decision on doing such confirmatory measurements on that and the results of dose rate measurements.

Sincerely,

Peter G. Vernig

PS You should adapt this so people can attach Word or other word processing files if you want to facilitate feedback.