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PROPOSED RULE PR 33
(61FR58346)

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February 4, 1997

Secretary,
Nuclear Regulatory Commission
Attn: Docketing and Service Branch
Washington, DC 20555-0001

Dear Secretary,

The following comments are made in response to the proposed changes to 10 CFR , Part 33, published in the Federal Register, Vol. 61, No. 221, dated November 14, 1996.

Much of the proposed rule appears to be rooted in observations made by the NRC during the investigation of two situations where there was an intake of radioactive material by a radiation worker. It is our opinion these intakes were isolated cases and a situation where there was criminal intent on the part of a particular individual(s). Most, if not all, of the proposed rule appears to be a knee-jerk reaction to these two isolated cases. It is our view that, short of abolishing the use of byproduct material, no one can write a regulation that will preclude a criminal act. The NRC's reaction threatens the flexibility that licensee and NRC personnel currently have, to be able to tailor a license to meet specific operational needs. We believe most, if not all, of the proposed rule is unnecessary as most broad scope licensees have many of these provisions already included in their license.

Be that as it may, Pharmacia & Upjohn has performed an evaluation of the proposed rules and with respect to your request for comments on general considerations, the following is submitted:

1. *NRC Question #1, #2 and #3 - Should the responsibilities of licensee management for the radiation safety program be specified in Part 33 and, should specific minimum training and experience criteria for authorized users be incorporated into Part 33?*

   P&U Response - Guidance that defines, 1) management responsibilities for oversight of radiation safety programs, 2) responsibilities of the RSO, 3) responsibilities for the radiation safety committee, 4) training requirements for the RSO, and 5) training requirements for users and supervised individuals, should be provided in a Regulatory Guide as is current practice. We do not believe that incorporating detailed requirements in Part 33 is of value as this

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approach usually results in excessive regulatory burden on licensees. Regulations that endorse regulatory guides allow judgement and flexibility to be applied during the licensing process.

2 NRC Question #4 - *Should the NRC incorporate specific requirements for inventory and accountability of byproduct material in use, or modify its existing guidance?*

P&U Response - Current regulation and guidance on the inventory and accountability of byproduct material is adequate. Because of the variability in the way byproduct material is used in industry and academia, a knee-jerk reaction by the NRC, to the criminal actions of one or two people, may unnecessarily burden many other licensees who have demonstrated good performance.

3. NRC Question #5 - *Should the NRC consider the risks associated with internal exposure pathways separate from those associated with external radiation?*

P&U Response - The methodology used in 10 CFR, Part 20 should be used for estimating internal exposure.

4. NRC Questions #6 - *Are there other specific aspects of the draft Regulatory Guide DG-005 that should be codified in Part 33?*

P&U Response - As noted in 1 above, all detailed guidance to meet radiation safety objectives should be provided via Regulatory Guides. The guidance provided in RG DG-0005 should not be codified but referenced in the regulations.

5. NRC Question # 7 - *Should broad scope licensees be allowed to make changes in their radiation safety program similar to those authorized for production and utilization facilities in 50.59?*

P&U Response - Pharmacia & Upjohn applauds the idea of allowing the Radiation Safety Committee the ability to "make changes to the facility or procedures as described in the license application", "without prior commission approval". However, the proposed wording of 33.59 (a), which reads, "unless the proposed change involves a change in a specific license condition", seems to dull or completely nullify the potential benefits that could be realized from this philosophy. It is suggested the wording of 33.59 (a) be revised to allow the RSC to make changes to the license (with subsequent notification to the NRC) as long as it is not in a "less conservative direction" than the existing condition.

6. NRC Question #8 - *Should the different types of broad scope licenses currently in Part 33 be deleted and replaced with a single type?*

P&U Response - It appears prudent that the NRC take steps to change the licensing classification system from Type A, B and C broad scope to "specific license of limited/broad scope".

7. NRC Question #9 - *Should a category for "Master Materials Licenses" be incorporated into Part 33 with the respective necessary requirements?*

   P&U Response - It's incumbent upon the NRC to ensure the regulations under its jurisdiction reflect the methods it is using to regulate the use of byproduct material. As such, the "master license" philosophy should be codified.

8. NRC Question #10 - *Should requirements for "Multi-Site Facilities" be codified in Part 33 or should this be defined only in Part 30?*

   P&U Response - It appears that the regulations covering a multi-site license will be in addition to those specified in 10 CFR 33, under the type "specific licenses of broad scope". As such, the requirements for multi-site licenses should be included in this part.

9. NRC Question #11 - *What balance should be maintained between a performance-based and a prescriptive approach to regulating broad scope licensees?*

   P&U Response - We believe that regulation and guidance should always be "performance based". Regulations should be written, and regulators should be operating, in a manner which allows licensees maximum flexibility in order to meet program objectives in a cost effective manner.

   As an example, the proposed rule requires the licensee to have a written procedure for "receiving and safely opening packages of byproduct material" which must be "reviewed and approved by the radiation safety committee" (33.12 (h)). As long as written procedures are in place which accomplish the objective (in this case, receive and safety open packages), it may not be efficient, nor cost effective, to have each member of the radiation safety committee review and approve the procedure.

   All proposed rules should be reviewed with this example in mind.

With respect to specific sections of the proposed changes to 10 CFR, Part 33, Pharmacia & Upjohn provides the following comments:

1. Section 33.2 -

   The last part of the sentence which defines the Radiation Safety Committee is redundant. It is suggested that the words "including responsibility for approval of all proposals for radionuclide use and users" be eliminated as this responsibility is fully defined in 33.22(4)(b)(2).

2. Section 33.12 (h) -

   A "performance based" approach would allow licensee management to determine if it was necessary for the radiation safety committee to "review and approve" written procedures. It is suggested that a requirement for such not be codified.

3. Section 33.17 (b)(2) -

Pharmacia & Upjohn does not use byproduct material for "medical use" and therefore, is not regulated by 10 CFR 35. However, Pharmacia & Upjohn (as well as other pharmaceutical companies) does use byproduct material for "human research" in accordance with 21 CFR, Part 361, where the amount of byproduct material is minute compared to normal therapeutic or diagnostic dose. 21 CFR 361, which is the Food and Drug Administration's regulations governing the use of radioactive material in human research, has specific requirements which provide adequate controls over this research involving humans, i.e.; oversight by a Radioactive Drug Research Committee and an Institutional Review Board. To avoid confusion, and differentiate between "human research" and "medical use", it is strongly recommended that 33.17 (b) be modified to recognize "human research" as conducted by the pharmaceutical industry and reference the provisions of 21 CFR 361, while avoiding all reference to 10 CFR 35.

4. Section 33.22 (a)(1) -

The term "medical broad scope licensees" is inconsistent with the previous proposed types of licenses defined in 33.11. To keep terminology correct, this might better be phrased "specific broad scope licenses for medical use".

5. Reporting requirements -

There appear to be some redundancies with regards to internal radiation safety program reviews and reports. Specifically, 33.21(c)(3), 33.22(b)(3), 33.22(b)(1) and 20.1101 all refer to a need to provide an annual review/report covering the same issues. It is suggested that the intent be clarified and the redundancies eliminated.

It is requested that these comments be addressed as part of the comment resolution for the proposed rule for 10 CFR 33.

Sincerely,

PHARMACIA & UPJOHN, INC.

LJKenagta
Radiation Safety Officer - PPC-US

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cc: CWS
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