



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

November 30, 1984

*orig. ret'd to Davis
w. P35 memo*

AA73-1
PDR
M. 25

*rec'd
11/30/84
[signature]*

NOTE TO: R. E. Cunningham
FROM: John G. Davis
SUBJECT: PART 35 REVISION COMMENTS

I have read the Part 35 revision. This has been well done--a clear expression of a complex subject. The challenge now is to present this so that it is understandable.

I suggest you develop a briefing that emphasizes:

1. The purpose and need for the revisions.
2. The staff proposal:
 - o What it requires
 - o What it changes
 - o What "new requirements" are included
3. Description of the medical regulatory process:
 - o Now
 - o Under the proposed vision
4. Impacts:
 - o Safety
 - o Efficiency and effectiveness
 - o Costs
5. Disputes

(Each specifically identified)

The "disputes" portion should be given to the "disputees" to be certain we have properly captured the substance of their position.

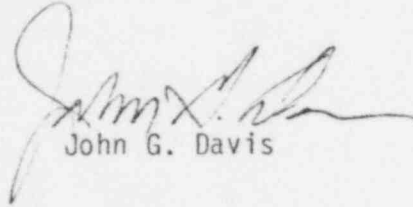
We then should brief the EDO and the Commissioners' Assistants and promptly move this.

R. E. Cunningham

-2-

November 30, 1984

I have attached some comments. I expect no written reply to these comments but would like for you to discuss them with me.



John G. Davis

Enclosures:
As stated

cc: D. B. Mausshardt

COMMENTS OF PART 35 REVISION
(Numbers" of comments are in margin of "package")

Commission Paper

1. p.2, (3) Insert "Under the staff recommended alternative (Alternative 2 of Enclosure 10), . . ."
 2. p.4 Are the six items listed after references to the Rogovin report from the report? Should we cite the Rogovin report as a basis for this revision-- i.e., is it a needed citation or a "red herring?" *Don't know about Rogovin*
 3. p.5 Who doesn't endorse the proposed regulatory text?
John Nelson (letter 13 1/24 26) to NRC Board members both supervisors, should be
 4. p.6 Insert, "A discussion of the opposition to this approach is included in Enclosure 8."
Region III switch
- Enclosure 1
5. p.8 This does not mean a review of "model procedures" to which a licensee has committed, does it? Perhaps, it should be made clear that the "model procedures" approach reduces review.
 6. p.8 Insert something like, ". . . following an NRC required licensee review process . . ."
 7. p.16 Can a term other than "pure" be used to describe this type broad license?
 8. p.16 Can a term other than "hybrid" be used to describe this type broad license?
 9. p.19 The use of the word "exception" has very specific meaning which has developed from the reactor program. Please determine from ELD whether some other expression (such as ". . . the license will be viewed as taking precedent over the regulation.") If some other expression is not used, this concept (general exemption) should be specifically called out for Commission consideration. *see 3504 "as written requirements" and see rule section in 3504*
 10. p.20 The additional requirement should be "highlighted" in any briefing we may give the Commissioners. *also say "highlighted"*
 11. p.25 Same comment as 10, above.
 12. p.109 Is this the same requirement that has caused questions by cardiologists? If so, in any Commission briefing please note this. *as p. 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000*
 13. p.118 Should this not note that the supremacy of the prior license ceases upon Commission issuance of an amendment, renewal, etc? Maybe, there needs to be an addition such as ". . ., until such time as the Commission supercedes the license requirements." As written, (and if read in isolation of the explanation on p. 18-19, Enclosure 1), the exemption, "as expressed in the rule, would appear to be "open ended."

Enclosure 3

14. p.1 This information re misadministration should be "highlighted" for any Commission briefing. ✓
15. p.3 I am not quite certain exactly what is planned operationally in the review prior to the licensing decision, particularly with regard to "pre-licensing review." I understand that there will be review of training and experience but I'm not certain I understand what is planned for the pre-licensing review of procedures. I had assumed that the applicant could reference, for example, Reg Guide 10.8 with whatever additional procedures may be needed that would be licensee site specific. The "site specific" procedures would be subject to prelicensing review. Alternately, the applicant could devise his own procedures which would be reviewed in their entirety to assure conformance with the rule. Is something else planned? *define, prec. briefing* ✓
(In a review of the Part 35 package the only place I recall this idea being clearly expressed is Footnote 21, p.12, of Enclosure 4. This concept is central to the revised approach and should be clearly explained early in the paper.) *Footnote 21 copied in ENCL 3p3, ENCL 4p3, FRN ENCL 1p2, and staff papers p 2 & (3)*

Enclosure 4

16. p.3 Same as comment 15. ✓
17. p.3 Is the problem that the states foresee based on the issuance of the license with "pre-licensing review" of procedures or based on the authority of licensees to make certain changes in "approved" procedures without "pre-approved review of the changes? or both? *this text revised* ✓

Enclosure 7

18. p.2 The literature reference should be more clearly expressed. ✓

Enclosure 8

19. p.1 The response discusses citations as of minor significance. This should be rewritten to deal more specifically with the comment of "serious violations," "overexposures" and "unnecessary public exposure." ✓
20. p.2 Typo--"litte" should be "little." ✓
21. p.2 I don't understand the comment nor the reply. ✓

Enclosure 9

22. p.1 Same general impression as that for comment 19. ✓

General

- a. It is implicit that the approach proposed here would require more (or different) inspection. Is it assumed that the approach will free licensing resources for transfer to inspection activities? Is this matter explicitly discussed in the paper? *No. Management prerogative.* ○
- b. Note Comment 2 above. If the explicit references to the Rogovin report is changed in the Commission paper, parallel change should occur at any other Rogovin reference. ✓