

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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OVERSIGHT OF MATERIALS UNDER A GENERAL LICENSE

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BRIEFING ON STUDY OF ADEQUACY OF REGULATORY
OVERSIGHT OF MATERIALS UNDER A GENERAL LICENSE

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Thursday, September 21, 1989

The Commission met in open session, pursuant to notice, at 10:00 a.m., Kenneth M. Carr, Chairman, presiding.

COMMISSIONERS PRESENT:

KENNETH M. CARR, Chairman of the Commission
THOMAS M. ROBERTS, Commissioner
KENNETH C. ROGERS, Commissioner
JAMES R. CURTISS, Commissioner

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STAFF SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

JAMES TAYLOR, Acting Executive Director for Operations

ROBERT BERNERO, Director, NMSS

JOHN AUSTIN, NMSS

STEVE BAGGETT, NMSS

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P-R-O-C-E-E-D-I-N-G-S

10:00 a.m.

1
2
3 CHAIRMAN CARR: Good morning, ladies and
4 gentlemen.

5 The purpose of today's meeting is to brief
6 the Commission on the staff's assessment of regulatory
7 oversight of nuclear materials under a general
8 license. During the last several years, the
9 Commission has made several initiatives to improve
10 regulatory oversight of nuclear materials. The
11 Commission is particularly interested in assessing the
12 adequacy of regulatory oversight for nuclear materials
13 under general licenses.

14 This issue was raised by NRC's Material
15 Safety Regulatory Review Study Group in 1986. The
16 Commission looks forward to hearing the staff's
17 recommendation on this issue and, if necessary, taking
18 actions to improve our regulatory program for
19 materials under general license.

20 Copies of the presentation slides should be
21 available at the entrance to the meeting room.

22 Do my fellow Commissioners have any opening
23 remarks?

24 If not, Mr. Taylor, please proceed.

25 MR. TAYLOR: Good morning, Mr. Chairman.

1 With me at the table from the Office of NMSS are the
2 Director, Bob Bernero, and to my left John Austin and
3 Steve Baggett. All will participate in the
4 presentation.

5 To introduce this subject, I'd like to cover
6 just a few quick points. As the Commission knows, the
7 general license program covers devices containing
8 radioactive material which present relatively--
9 potentially relatively low hazards. They're used
10 widely throughout the country for important personnel
11 safety and industrial process control functions as
12 examples. They're gauges that control liquid levels,
13 weight and thickness, are examples of industrial
14 applications, and you'll hear more about that today.

15 It has evolved within the Agency's
16 predecessor and within this Agency over a period of
17 the last 30 years and there has -- this is one of the
18 first comprehensive reviews, certainly since this
19 Agency started, that has been conducted.

20 There have not been major health and safety
21 problems associated with this program. However, the
22 Commission is aware that problems have arisen from
23 time to time which has raised the question of how we
24 should improve and update this program. An example,
25 of course, the 3M static eliminators and that problem

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1 which the Commission I'm sure remembers.

2 Also, recommendations were provided by the
3 Material Safety Regulation Review Study Group that we
4 make a general review of our policies and activities
5 on general licenses. We've also had that
6 recommendation from several agreement states.

7 So, today, the staff will brief you with an
8 overview where we are in the program review and the
9 lead presenter is John Austin.

10 MR. AUSTIN: Mr. Chairman, Commissioners,
11 we'll be using 12 briefing charts for today's meeting.

12 (Slide) If I could have the first briefing
13 chart, please.

14 The first briefing chart outlines what we
15 will be covering today. We'll give a general overview
16 of the general license program itself. We'll be
17 identifying some of the problems that we perceive with
18 the program. We'll discuss some of the questions that
19 have been raised regarding the program and then we'll
20 describe the plans for improving and updating the
21 overall general license program. Finally, we'll be
22 discussing some of the staff initiatives and the
23 resource associated with those staff initiatives.

24 (Slide) If I could have the second briefing
25 chart.

1 I'd like to first describe where the general
2 license program fits within the overall regulatory
3 framework. We have essentially three different
4 licensing regimes. The first is the specific license.
5 Here, we require applicants to come to the Agency and
6 request authorization to possess quantities of
7 byproduct material, to describe the activities that
8 they're going to carry out with that material and
9 require these applicants to have an understanding of
10 basic radiation protection principles.

11 Upon assuring that the applicant meets all
12 applicable regulations, we issue a sheet of paper to
13 that applicant in the form of a license that
14 identifies what activities they're allowed to carry
15 out and what materials they're allowed to possess.

16 These licensees are under active NRC control
17 in the sense that we periodically inspect them. We
18 issue the license for a finite period of time, five
19 years. They must come back to us and seek renewal of
20 that license after that period of time. Thus, the
21 specific license program is an active regulatory
22 control.

23 (Slide) The next regime is the general
24 license program. Here, a possessor of a generally
25 licensed device does not have to contact NRC prior to

1 receiving it. They do not have to have training in
2 radiation protection principles because the devices
3 that are authorized to be distributed to general
4 licensees have safety built into them that is at a
5 sufficient level that the user can use them safely
6 without understanding radiation protection principles.

7 The general licensees are under what we'd
8 call passive control. We know who they are, but we
9 rarely contact them and they rarely contact us.
10 Typically it's more of a reactive regulatory program.

11 And the lowest level of regulatory control
12 comes under what we call the exempt practices. Here,
13 there is no control over the device once it is
14 distributed to individuals. An example of that is the
15 smoke detectors containing americium. Those are
16 exempted from the regulations after we have authorized
17 a manufacturer to construct and distribute them.
18 There's essentially no concern over the handling or
19 the disposal of the exempt devices.

20 This regime was the subject of a Commission
21 meeting last July, below regulatory concern or exempt
22 practices. The focus of the effort that we're
23 discussing today is in the middle regime. In
24 particular, the SECY paper that recently came to you,
25 SECY-89-289, deals with Part 31.5, general licensees.

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1 That part covers the vast majority of generally
2 licensed devices and encompasses those devices which
3 have a potential for causing a radiation hazard.

4 (Slide) If I can go to the third briefing
5 chart.

6 There are many provisions throughout the
7 regulations that create general licenses. There are
8 general licenses for importing, for exporting, for
9 ownership, but not necessarily for use. The general
10 license concept originated as an administrative
11 convenience, that is in anticipation of a large number
12 of these being designed with safety built in and a
13 large demand for them. Back in the very late '50s,
14 early '60s, the AEC decided that rather than process a
15 piece of paper for each and every gauge that was to go
16 into commerce, because of the safety being built into
17 the device, it would be much more convenient to create
18 what's called the general license. We don't
19 relinquish total control over that and I'll be getting
20 into some of the provisions or constraints placed on
21 general licensees.

22 But 10 CFR 31.5 creates general licenses for
23 certain measuring, gauging, eliminating and control
24 devices. These devices are generally those of most
25 significant concern in terms of the potential for harm

1 to the public.

2 10 CFR 32.51 provides for manufacturers to
3 distribute to generally licensed devices via a
4 specific license. Here, an organization would apply
5 for a specific license to the Agency to distribute a
6 device to general licensees. We review the design of
7 that device to ensure that it meets the applicable
8 regulations and then issue what we call a G license,
9 which is a license to that manufacturer which
10 authorizes the distribution to generally licensed
11 individuals.

12 We require those manufacturers to report to
13 us, or to an agreement state if that is the licensing
14 entity, all transfers that they make to general
15 licensees. That's how we know who possesses generally
16 licensed devices.

17 CHAIRMAN CARR: Or who did possess them.

18 MR. AUSTIN: Who did, but there are
19 constraints on what the general licensee can do after
20 they receive it. There are prohibitions on disposal
21 and they can only transfer that device to another
22 specific licensee. But admittedly, we may not be
23 aware of that transfer.

24 CHAIRMAN CARR: Who serves him with those
25 prohibitions and the notice?

1 MR. AUSTIN: When we review the
2 manufacturer's application, we require the
3 manufacturer to inform through a package insert the
4 general licensee that they are in possession of Atomic
5 Energy Act material and whatever other provisions that
6 place constraints on the general licensee, such as
7 constraints on retransfer, on the -- the manufacturer
8 must inform the general licensee that if there is an
9 incident with the device or a loss of the device, that
10 they must report to the Nuclear Regulatory Commission
11 that.

12 CHAIRMAN CARR: That's just a package insert
13 in the --

14 MR. AUSTIN: Yes.

15 CHAIRMAN CARR: -- whatever he bought?

16 MR. AUSTIN: It is a package insert that --

17 CHAIRMAN CARR: Like my chain saw package
18 insert that says this is a dangerous piece of gear?

19 MR. AUSTIN: Right. And that package insert
20 may only be read by the purchasing agent.

21 CHAIRMAN CARR: If at all.

22 MR. AUSTIN: If --

23 COMMISSIONER ROBERTS: Or maybe the
24 receiving clerk.

25 COMMISSIONER ROGERS: Yes.

1 MR. BERNERO: John, if I could add, I recall
2 that when we were discussing the 3M affair, we had the
3 handout, the package insert and shared it with the
4 Commission. When you look at it you can say, "Yes,
5 indeed, the key information and requirements are all
6 there," but that's exactly the point. Is there any
7 assurance that the receiver reads it, understands it,
8 and the right person understands it? We also found in
9 the 3M thing that there were people who were so
10 disorganized that they were leasing these devices and
11 putting them in the warehouse and a year later sending
12 those back and leasing another set and not using them.
13 One company in particular discussed that with me.

14 So, that's one of the control aspects that
15 we're concerned about, is the lack of institutional
16 memory at the general licensee. Do they know they
17 have it? Do they know what it is?

18 CHAIRMAN CARR: Okay.

19 MR. AUSTIN: It's also part of the program
20 we think needs strengthening, which we'll be
21 discussing later.

22 (Slide) On briefing chart number 4, in
23 continuing the description of our general license
24 program, NRC has licensed about 54 manufacturers to
25 distribute devices to generally licensed individuals.

1 Agreement states have licensed about 76 manufacturers
2 to distribute devices to generally licensed
3 individuals. NRC has a total of about 30,000 general
4 licensees that possess about 400,000 devices.

5 COMMISSIONER CURTISS: Does that include
6 agreement state licensees?

7 MR. AUSTIN: Does not.

8 COMMISSIONER CURTISS: Do you have any idea
9 how many the agreement states have issued, how many
10 devices there are out there?

11 MR. AUSTIN: I think we generally have
12 multiplied by a factor of two. Is that about --

13 MR. BAGGETT: That's the rule of thumb.

14 MR. AUSTIN: Rule of thumb.

15 COMMISSIONER CURTISS: Sixty thousand
16 general licenses, 800,000 devices?

17 MR. BERNERO: Very rough estimate.

18 MR. BAGGETT: You have to recognize some of
19 the agreement states do not honor a general license.
20 They will issue a specific license, particularly for
21 some gauging devices.

22 COMMISSIONER CURTISS: Do we have a way of
23 simply asking the agreement states how many licenses
24 they've issued of a general nature and tracking that?

25 MR. PARLER: There certainly is the

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1 authority to have a way.

2 COMMISSIONER CURTISS: Have we asked it?

3 MR. BAGGETT: It would be labor intensive--

4 COMMISSIONER CURTISS: Okay.

5 MR. BAGGETT: -- and have to review the
6 quarterly reports one by one.

7 CHAIRMAN CARR: They might be. They also
8 might have the number at their fingertip.

9 MR. BAGGETT: They may have. In past -- a
10 number of years ago we went out and looked at some of
11 the devices and had some of the agreement states also
12 look at the products in the field. They were having
13 similar problems with the record keeping that NRC was.
14 It's such a large volume, it's labor intensive to go
15 through and weed out which licensees are maintained.

16 The quarterly reports may be one page or
17 they could be 500 pages.

18 COMMISSIONER CURTISS: We're roughly talking
19 about 90,000 general licenses and about 1.2 million
20 devices, using the rule?

21 MR. AUSTIN: Approximately. Enclosure 1 to
22 SECY-89-289 tabulates the various types of generally
23 licensed devices and it also provides a rough estimate
24 of the numbers of each type of device. For background
25 purposes, enclosure 1 also contains a brief

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1 description of how these devices are used.

2 Right now, Steve Baggett has brought in a
3 spectrum of devices that are generally licensed and we
4 thought it would be useful for you all to see some of
5 them.

6 So, Steve, if you could --

7 MR. BAGGETT: Thank you.

8 (Slide) Could I have the first 35
9 millimeter slide, please?

10 The general license under 31.5 -- and these
11 samples do not contain radioactive material. 31.5 has
12 a gamut of devices of different sizes and models.

13 This is a static eliminator air nozzle
14 that's used to basically get dust off of film and
15 plastics and used to keep static charge from building
16 up. It contains polonium 210, around 20 to 200
17 millicuries of polonium 210 and it's similar to the
18 device that 3M was selling.

19 There's another device that's used quite a
20 bit. It's called an electron capture detector cell.
21 It's used in gas chromatographs and it's increasingly
22 used in the last few years because of an increase in
23 the EPA's interest in pesticide monitoring in watering
24 and air quality releases.

25 This goes into a product called a gas

1 chromatograph. We regulate this -- and this is just
2 an example of the type of labeling that's required on
3 the product. There are certain labeling conditions
4 and criteria. It contains about 12 millicuries of
5 nickel or 100 millicuries of tritium.

6 (Slide) We have exit signs. The next 35
7 millimeter slide, please.

8 Exit signs contain about 20 curies of
9 tritium gas. These little glass tubes are filled with
10 five curies apiece. They have a phosphor and they
11 emit a green glow. They're used for emergency exit
12 markers in residential buildings, schools, hospitals,
13 you name it.

14 We also have, which is -- a large part of
15 the devices are what we call gauging devices.

16 (Slide) Next 35 millimeter slide, please.

17 These gauging devices typically measure the
18 thickness of paper, density of materials. It gives
19 you an idea of the range in construction of relatively
20 small to very robust design.

21 (Slide) Could I have the next slide,
22 please?

23 I want to give you an idea of the typical
24 conditions, environmental conditions, that these
25 devices are designed and constructed to operate in.

1 This is the -- gauging devices have a mechanism so you
2 can tell what the concentration is of the density of
3 material. This is that monitor for a particular piece
4 of equipment to show you how dirty the environment is.

5 (Slide) Next slide, please.

6 This shows you the location of the gauge.
7 If you look right in the middle of the screen, you'll
8 see a kind of a whitish dot.

9 (Slide) Next slide, please.

10 Here's what the gauging device looks like.
11 This is a coal slurry plant in West Virginia and the
12 gauge is about two years old. So, it's very important
13 that they follow their general license requirement of
14 maintaining labels, which this company is trying to do
15 by putting an additional label on the device. It just
16 shows you that we've had good operational history with
17 these things in this type of environment, although the
18 paint -- they're not very pretty or attractive after a
19 number of years. They tend to function and function
20 well for a long period of time.

21 That's all I have.

22 MR. AUSTIN: Thank you, Steve.

23 (Slide) If I could have briefing chart
24 number 5.

25 To conclude the general description of the

1 program, as I mentioned previously, there are a few
2 constraints placed on the general licensee. Part 20
3 requires the general licensee to report a theft or a
4 loss of a device to the NRC. The general licensee, as
5 we just discussed, learns of this requirement on them
6 only through the package insert, and that can be lost
7 or not read. We receive very few reports from general
8 licensees involving problems with these devices, but
9 we suspect that there may be more problems occurring
10 than what we hear.

11 And finally, the general licensee may only
12 transfer the device back to a specific licensee.

13 Other than those two provisions, the general
14 licensees are exempted from Part 20, our radiation
15 protection principles.

16 (Slide) On briefing chart 6, I'd like to
17 get into some of the problems that we've experienced
18 with general licenses. The largest problem that we
19 perceive is the loss of control of the devices.
20 General licensees are often unaware of the potential
21 hazards. They do not always follow the regulations on
22 transfer, maintenance, disposal and record keeping.
23 Warning labels become illegible, making them
24 vulnerable to loss or entering into unauthorized
25 disposal channels.

1 The second problem is the quality of the
2 devices. In the 1960s, when this program was just
3 getting underway, when a device was approved for
4 general distribution, the regulations were changed to
5 specify a quality assurance program that the vendor
6 had to use to ensure the safety of the device. That
7 practice of placing into the regulations quality
8 assurance requirements for generally licensed devices
9 appears to have stopped in the late '60s. And
10 further, some of the rules that have changed since
11 then allowing devices to be generally licensed may not
12 have always been consistent with things we had done in
13 the past.

14 And finally, these generally licensed
15 devices are not required to have third party testing.
16 We think that some of the problems that we've
17 experienced in the past, had the device been subjected
18 to a third party test, we would have seen some of the
19 vulnerabilities early on.

20 CHAIRMAN CARR: Did I understand you to say
21 we don't require a QA program now?

22 MR. AUSTIN: The regulations require that
23 the applicant describe in sufficient detail its
24 quality control program. There are some ANSI
25 standards, I believe it's ANSI standards, that in some

1 cases address quality assurance, but it is not what
2 I'd call a robust, explicit part of the regulatory
3 regime for these devices.

4 CHAIRMAN CARR: But you implied it used to
5 be.

6 MR. AUSTIN: Yes. The regulations still
7 contain frequency charts that certain devices had to
8 be subjected to --

9 CHAIRMAN CARR: So, the regulations are
10 there, we're just not enforcing them. Is that what
11 you're telling me?

12 MR. AUSTIN: The regulations are there for
13 some devices, but not for others. Some of the devices
14 have explicit quality assurance requirements attached
15 to them. Other devices have been added to the general
16 license provision, but they were not accompanied with
17 a quality assurance provision in the rules.

18 MR. TAYLOR: That's a mix.

19 CHAIRMAN CARR: But the regulations don't
20 address each individual device, I wouldn't think.

21 MR. AUSTIN: Initially they did, yes.

22 CHAIRMAN CARR: The license would address
23 the device.

24 MR. BERNERO: Unfortunately they do. We
25 don't have a generic rulemaking in place or a generic

1 rule in place that sets down performance standards or
2 criteria for overall QA programs of all devices. What
3 has happened -- you're licensing by regulation really
4 in these devices and what happens is some of them are
5 specifically required to have things, others are not.

6 CHAIRMAN CARR: But in their license, not in
7 the regulations.

8 MR. BERNERO: Some of it's in the
9 regulations too. But there's a real need there for
10 consistent, overall requirements. That's one of the
11 initiatives that's clearly needed.

12 CHAIRMAN CARR: Well, could you write it
13 into the license instead of the regulation?

14 MR. BERNERO: Oh, you could consistently do
15 it in every license, but I think it would be better
16 and we've discussed it in the paper to have a
17 performance oriented QA rule and then let the license
18 implement that.

19 MR. AUSTIN: I think in the past, General
20 Counsel has cautioned against generic license
21 conditions that are applied one by one without going
22 to rulemaking. My recollection is that that created a
23 problem in the past. If you're going to do the same
24 license condition over and over and over again in a
25 license, is that not --

1 CHAIRMAN CARR: Well, certainly that's
2 preferable, but I can't understand how we started
3 regulating them correctly and then quit, if what you
4 tell me is accurate.

5 MR. AUSTIN: Again, this appears to have
6 changed in the late '60s, early '70s.

7 CHAIRMAN CARR: Well, when you say it
8 appears to have changed, that doesn't necessarily mean
9 to me a change. Whether it changed or we quit, I
10 don't know what we're doing. But you see my problem.

11 MR. AUSTIN: I see your problem.

12 MR. PARLER: Whatever the change was, I
13 think I should say it was not because of legal
14 reasons. Perhaps what Mr. Austin said was a view that
15 was expressed some years ago. It's probably grounded
16 on common sense. If you have conditions that you
17 repeatedly put in individual licenses, perhaps --

18 CHAIRMAN CARR: I've heard Commissioner
19 Rogers express that opinion.

20 MR. PARLER: Sir?

21 CHAIRMAN CARR: I've heard Commissioner
22 Rogers express some of those in the other way, "If we
23 keep waiving this thing, why don't we waive it for
24 everybody?"

25 MR. PARLER: I think what may be kind of

1 confused here is that there is still in the
2 regulations, in the requirements for the specific
3 license, for the manufacturer, at least broad areas
4 that have to be addressed. The practice, as I
5 understand it, that was discontinued in the late '60s
6 was for the rule that established a general license
7 for the device itself, that rule used to be
8 accompanied by a great deal of QA type detail. For
9 whatever reason that I don't know about, other than
10 the fact that people go to different jobs, leave, that
11 practice was changed.

12 CHAIRMAN CARR: Okay. Let me say it's part
13 of the third party test. Why do I want a third -- why
14 don't I just require them to provide me the
15 documentation that they've tested it correctly and
16 give me the data?

17 MR. AUSTIN: There is always an advantage of
18 having a disinterested third party doing the test. It
19 provides an additional level of protection, rather
20 than have the proponent, the one that benefits from
21 having positive data -- rather than have them generate
22 that data --

23 MR. BERNERO: That's a widely done practice.
24 You know, the Underwriter's Laboratory and things like
25 that, for devices that are in commercial distribution

1 and that have a safety issue associated with them.
2 That's what the real attraction of third party testing
3 is. It's independent.

4 CHAIRMAN CARR: But it doesn't seem to me
5 that we require that of our reactor licensees. We
6 require them to be honest with us and do the tests we
7 want them to do and provide us the documentation.

8 MR. BERNERO: Yes. Of course --

9 COMMISSIONER ROBERTS: There is third party
10 inspection too. You can't manufacture a reactor
11 pressure vessel without having a national board
12 inspector inspect it.

13 MR. AUSTIN: Some of their electrical
14 devices have been subjected to UL testing.

15 MR. BERNERO: Yes. That's a major
16 consideration in that initiative of is there a
17 commensurate reliability or quality that comes with
18 that. These devices seem to fit the pattern that is
19 widely used in the rest of our commerce for third
20 party testing.

21 CHAIRMAN CARR: It seems so simple. Why
22 haven't we required it before?

23 MR. BERNERO: Good question. I think this
24 whole system, in the QA, in the third party testing,
25 in the reporting, in so many of the things, we're

1 dealing with a system of regulation that sort of grew
2 over the last 30 years or so. It's not surprising if
3 we look back to see inconsistencies or gaps. You
4 know, we're a lot smarter today than we were then.

5 MR. AUSTIN: It started out as a very modest
6 program back in the 1960s. There were about 4,000 or
7 5,000 devices that were generally licensed. We've
8 gone up over a factor of 100 --

9 CHAIRMAN CARR: All right. Let's proceed.

10 MR. AUSTIN: The third problem that we
11 perceive with the general license program has to do
12 with the greater than Class C waste issue. Currently,
13 when the staff authorizes distribution of devices to
14 generally licensed individuals, the ultimate
15 disposition of that licensed material is not
16 addressed. It could be, and it is in some cases, that
17 the cost of disposal of that device can be several
18 times the purchase price of the device. And it's not
19 clear that the buyer is aware --

20 CHAIRMAN CARR: So, do you want to put a
21 warning label in the brochure they're not reading in
22 the package?

23 MR. AUSTIN: We have a program to -- we hope
24 will make them read it and if we put dollar signs in
25 there saying, "A bill is coming due later," maybe that

1 will further encourage them to read the package
2 insert.

3 MR. TAYLOR: It may cost you more to get rid
4 of it than to buy it.

5 MR. BERNERO: I'm not sure of the outcome,
6 but we have an overall objective to have what we
7 sometimes call internally "truth in material
8 licensing," so that if someone is buying or leasing a
9 nuclear device of this sort, they know the full gamut
10 of the costs and the obligations and they know it up
11 front and perhaps are billed up front. One of the
12 alternatives -- this is not a commitment, but it's an
13 alternative to be considered -- is the vendor, the
14 distributor or manufacturer of the generally licensed
15 device, if it's greater than Class C, may only lease
16 it, for example, and then he or it, the company,
17 retains the obligation for disposal and it's up to
18 that company to charge an appropriate fee built into
19 the price for the greater than Class C disposal.

20 Or, depending on how the DOE program comes
21 out, there might be some fee that can go with the
22 device so that it is entitled to DOE disposal at the
23 end of its useful life. Those are alternatives.

24 CHAIRMAN CARR: I guess --

25 MR. BERNERO: We want to get that cost up

1 front.

2 CHAIRMAN CARR: -- the vendor could require
3 sufficient deposit that it makes the guy want to turn
4 it in when he's through with it.

5 MR. BERNERO: Yes, the equivalent of a bond
6 or something like that, yes. Any one of these things
7 might be the solution, but right now we don't have the
8 solution and these people are buying a device, a
9 greater than Class C source, that literally cannot be
10 disposed of and, frankly, there are only a few places
11 you can turn the things in now and it costs an
12 enormous sum to do so.

13 COMMISSIONER ROBERTS: Well, would you
14 hazard a guess? Of the approximate 1.2 million
15 devices how many of them are involved in greater than
16 Class C waste?

17 MR. BERNERO: Well, I think we've got a
18 tabulation in the attachment that gives a cut at that.
19 In enclosure 1.

20 COMMISSIONER ROBERTS: One is the listing.

21 MR. BERNERO: Yes. If you'll look at Table
22 1.1, page 5 of enclosure 1. We've got hundreds,
23 getting into the low thousands of these devices.

24 COMMISSIONER ROGERS: I see a number in my
25 notes of 22,000.

1 MR. BERNERO: Yes. If you add -- I'm
2 looking at the middle devices, fuel densitometer,
3 gauging devices. The gauging devices dominate, 16,000
4 of them. Many of those are moisture density gauges,
5 you know, the things for pavement, that are marginally
6 greater than Class C. They may even constitute a
7 different class when we come down to it. There may be
8 a different thing you can do with them.

9 MR. PARLER: Of course, Mr. Chairman, if
10 the -- really, the greater than Class C are a
11 relatively small number. There is the option of not
12 generally licensing those, but specifically licensing
13 those that have the specific license spell out all of
14 the pertinent details.

15 CHAIRMAN CARR: Yes. My understanding was
16 that there's somewhere in the neighborhood of 6,000 or
17 so that might fit that category.

18 MR. BERNERO: Our estimate in the table is
19 of the order of 1,000 or more a year are sold and the
20 number out there in service, because many of them have
21 this long half life -- that's why they're greater than
22 Class C -- is of the order of 20,000. So, it's quite
23 a few.

24 But an awful lot of them, I would remind
25 you, are these moisture density gauges or pavement

1 gauges that are used in building contracts, paving,
2 road building, things like that.

3 COMMISSIONER ROGERS: But there'd still be
4 the disposal problem, wouldn't there?

5 MR. BERNERO: Oh, yes. They are greater
6 than Class C, but they are americium 241, which has a
7 very long half life and there may be a mechanism of
8 recycle that lends itself with them. There may be.
9 Some sources, they're not recyclable.

10 COMMISSIONER ROGERS: But as far as the
11 disposal problem is concerned, they're the same as
12 the --

13 MR. BERNERO: Oh, you still have to deal
14 with it because they are greater than Class C.

15 COMMISSIONER ROGERS: Okay.

16 MR. BERNERO: There's enough of the long
17 half life material there.

18 MR. AUSTIN: And the fourth problem we have
19 with the program is the relatively low regulatory
20 priority that it has been given. Budgetary
21 constraints have limited NRC oversight and in the
22 reviews of this paper by agreement states and the
23 regions, that was one of the most frequent criticisms.

24 CHAIRMAN CARR: We don't normally consider
25 it a problem if it's not a public health and safety

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1 problem and that's why it got a low regulatory
2 priority, I presume.

3 MR. AUSTIN: It is not a high public health
4 and safety problem based on sketchy information and
5 part of these initiatives are to enhance our
6 understanding of what is actually happening out there,
7 to provide better data on backing up the statement
8 that there is essentially no public health and safety
9 problem there.

10 (Slide) On the seventh briefing chart, some
11 of the questions that we've been asking and talking
12 about are the following:

13 Is the general license approach viable? We
14 occasionally get a comment that it ought to be done
15 away with, that there should be only two regimes.
16 Either you don't have concern over the material and
17 you exempt it, or you issue a specific license. In
18 fact, we could specifically license all of these
19 generally licensed devices, but that has associated
20 with it substantial resources that we think are not
21 justified given the additional controls that might
22 come under the devices.'

23 We could inspect the general licensees, but
24 then again we don't perceive a sufficient problem to
25 treat them the same way as we do specific licensees.

1 The second question is, are the
2 responsibilities of the various parties clear and
3 complied with? As we've discussed previously, the
4 package inserts may be forgotten or lost. We know
5 very little about the 400,000 devices and whether any
6 of the required leak break tests are, in fact, being
7 performed.

8 Are the devices that are generally licensed
9 acceptable for that program? Many suggest placing an
10 upper limit on the source content that ought to be
11 allowed in a generally licensed device. We talk here
12 about maybe prohibiting devices having greater than
13 Class C waste from being in the general license
14 program, bring them into the specific license arena
15 and put all the constraints we need to on it. That is
16 an option and we'll be addressing that in one of
17 our --

18 CHAIRMAN CARR: But that ignores whether
19 it's a threat to public health and safety or not if
20 you just arbitrarily draw --

21 MR. BERNERO: Well, there, it's really
22 linking the greater than Class C category as requiring
23 a greater degree of administrative control, therefore
24 a special license. So, indirectly, it is public
25 health and safety, but it's not the risk of the device

1 so much as the disposal of it.

2 MR. AUSTIN: The specific license could, as
3 we talked earlier, have a condition on it, that the
4 bond be posted that will ensure appropriate
5 disposition of the material when no longer needed.

6 COMMISSIONER ROGERS: Except that the
7 specific licensees have to have a basic understanding
8 of radiation principles you've stated. And yet the
9 devices that we're talking about are used in
10 applications where that's not required at all. So,
11 throwing those together --

12 MR. BERNERO: It's an additional burden.

13 COMMISSIONER ROGERS: -- escalates one
14 aspect of it to deal with quite a different one,
15 namely the disposal.

16 MR. BERNERO: Yes, exactly. And that's
17 why -- if anything, I'd say we're more inclined to go
18 for a financial lever. You know, something like an up
19 front charge or a lease deposit or something of that
20 sort which is usually a very effective way to keep--
21 it's like the deposit on a bottle. It's enough to
22 return the thing and recycle it.

23 CHAIRMAN CARR: It's more like the deposit
24 on your cable television box.

25 COMMISSIONER CURTISS: It does seem to me if

1 you're trying to get at the disposal problem with
2 greater than Class C, that the idea of returning it to
3 the manufacturer --

4 MR. BERNERO: Is more attractive.

5 COMMISSIONER CURTISS: And if there's a
6 separate or additional concern about safety during
7 operation where you draw a line between, say, sources
8 that are one curie and over, as you talked about in
9 the paper, and license those all specifically that are
10 in excess of one curie, that combination of approaches
11 might address the greater than Class C disposal
12 problem where there isn't any concern during or less
13 concern during use of the material.

14 MR. BERNERO: Yes.

15 COMMISSIONER ROGERS: We're just talking
16 sort of freely here, but as a general matter I would
17 hope that we could keep our categorization basis very
18 clean and always start with the health and safety and
19 we don't get the disposal and other things mixed up in
20 that. They may be important practical problems, but
21 how we view the situation should be based, it seems to
22 me, always entirely on the safety issues. And the
23 hierarchy we establish should be kept as pure as
24 possible on that basis and not mix in other
25 considerations and screw it all up.

1 MR. BERNERO: That's a good piece of comment
2 for us to have. As John said early in the briefing,
3 we are graded in the degree of regulatory control
4 according to the health and safety hazard. You know,
5 the inherent safety or the inherent risk of the device
6 and its use. That would be a significant confusion if
7 we start putting the waste disposal tag on things.

8 CHAIRMAN CARR: As I see the problem, it's
9 trying to decide if we --

10 COMMISSIONER ROGERS: Now, there is a health
11 issue there.

12 CHAIRMAN CARR: If there's a health and
13 safety issue out there we don't know about.

14 COMMISSIONER CURTISS: It does seem that
15 there's a health issue in both areas where there's a
16 health concern that we ought to pay attention to on
17 greater than Class C disposal and there's also an
18 operational concern that may be driven by a
19 distinction other than greater than Class C or less,
20 such as one curie more or less, that would govern what
21 we do during operation. But in either event, it does
22 seem to me we've got a health and safety concern.

23 MR. BERNERO: Yes, but they're so
24 different --

25 COMMISSIONER CURTISS: That's right.

1 MR. BERNERO: -- and the agents who need to
2 deal with the health and safety concern are so
3 different because it's not the paving contractor who
4 can deal with the greater than Class C waste disposal.
5 It's unnecessary to train him in repository design or
6 anything like that.

7 MR. AUSTIN: (Slide) This really leads into
8 the eighth briefing chart.

9 As we've seen here at the table today, there
10 are very many useful ideas on what one can do to
11 improve the general license program. With that
12 thought in mind, we prepared a draft of this paper and
13 sent it to the regions in all the agreement states and
14 asked for those people with the hard field experience
15 with these devices, what do you think, where should it
16 go, where can we get our best bang for the dollar.

17 We received a total of 24 responses back to
18 the draft. There was strong support for doing more in
19 the general license program. The most frequent
20 comment was to be more restrictive on the types of
21 devices that could be covered by a general license and
22 there was an occasional comment to just abolish the
23 general license program and go to a two licensing
24 regime, specific or exempt.

25 COMMISSIONER ROGERS: Could you give us some

1 idea of where these responses were coming from?
2 You've got 24, so that's not such a big number. Where
3 were they coming from?

4 MR. AUSTIN: They were coming from like the
5 state of Texas Board of Radiation Control, Florida
6 Radiation Protection Group. So, it was, in essence,
7 our counterparts in the agreement states.

8 COMMISSIONER ROGERS: What about industry
9 groups in any way? Did you get anything from them?

10 MR. AUSTIN: We did not circulate it to the
11 industry groups, although I think all that go out into
12 the field and interact with one licensee will have
13 their ear turned about their competitors and how bad
14 their competitors are. But at this point, there is no
15 impact on the licensees. Rather, many of these
16 recommendations would involve rulemakings, at which
17 time they would have an opportunity to address any
18 concerns they have.

19 CHAIRMAN CARR: That last comment, I assume,
20 was from the states?

21 MR. AUSTIN: Abolishing, yes. That was, I
22 believe, the state of Florida.

23 MR. BERNERO: I don't want to embarrass John
24 Austin, because he's on a rotational assignment to
25 Region IV, but I think Region IV suggested that we

1 further consider termination of the general license
2 program.

3 CHAIRMAN CARR: Did they make that comment
4 while he was on a rotational assignment?

5 MR. BERNERO: No. He has to go down and
6 live with it now.

7 MR. AUSTIN: They may change that comment in
8 the next two weeks.

9 (Slide) On chart number 9, we're now
10 getting into some of our plans for improving and
11 updating the program. We are initiating a rulemaking
12 to require the general licensee to respond to a
13 periodic questionnaire regarding the inventory,
14 maintenance, and disposal activities. SECY-89-289
15 recommends expanding the questionnaire to include
16 obtaining information on leak tests. You do perform
17 leak tests? What is the frequency? The view is that
18 any question related to compliance with the
19 regulations or obligations of the general licensee
20 ought to be reinforced on a periodic basis.

21 We think that this questionnaire will
22 heighten the awareness of the general licensee that
23 they possess a radioactive source, particularly if it
24 is a responsible individual that has to respond. And
25 rather than allow the package insert now to go willy-

1 nilly within an organization, the recommendation is
2 that a responsible individual within the organization
3 must read the package insert and must respond on about
4 an annual basis to a questionnaire as to their
5 compliance with their obligations. So we think that
6 would help control -- have better control over the
7 devices in the field.

8 The second thing that we're doing is that we
9 are computerizing these quarterly transfer reports,
10 rather than have a file sitting there full of sheets
11 of papers with names and numbers on it. We're
12 entering these into the computer, in part to gain
13 better control -- a better understanding of what is
14 out there, and in part to assist in this annual
15 questionnaire.

16 COMMISSIONER ROBERTS: But at this point,
17 you have no idea if you have knowledge of all the
18 transfers? Is that not correct?

19 MR. AUSTIN: There is a requirement that the
20 manufacturer notify us if they transfer to a general
21 licensee.

22 CHAIRMAN CARR: But that's the initial
23 transfer.

24 COMMISSIONER ROBERTS: That's the initial.
25 What about the general licensee who then may make some

1 disposition?

2 MR. AUSTIN: There is no requirement
3 associated with that.

4 Is that correct, Steve?

5 CHAIRMAN CARR: Except that he turn it back
6 to a specific licensee, the way I read your brief.

7 MR. AUSTIN: But I don't think they have to
8 report that to the NRC.

9 MR. BAGGETT: In Part 31.5, which is the
10 requirements on the general licensee, there is a
11 requirement that the user notify the regulatory body
12 that he has transferred the device, whether to a
13 specific licensee or to another general licensee.
14 There's some very specific conditions.

15 CHAIRMAN CARR: Can he transfer it to
16 another general licensee?

17 MR. BAGGETT: There's one condition that,
18 say if a gauge is mounted in a factory or an exit sign
19 in a building, a general licensee of that gauge can
20 transfer the entire product to a person buying out the
21 building, for example, and then notify NRC in this
22 case that he has made the transfer to this gentleman
23 or this company.

24 CHAIRMAN CARR: But the guy that read the
25 package insert normally doesn't sell the building.

1 COMMISSIONER ROBERTS: Yes.

2 MR. BAGGETT: That's true.

3 MR. BERNERO: Very tenuous.

4 COMMISSIONER CURTISS: How much confidence
5 do you think we have, if there are X number of
6 transfers between general licensees. Do we think we
7 know about 10 percent of them or 90 percent of them?
8 What's your degree of confidence?

9 COMMISSIONER ROBERTS: One percent.

10 CHAIRMAN CARR: Well, let's ask how many
11 reports have you gotten in the last six months?

12 MR. BAGGETT: We've received somewhere in
13 the neighborhood of 20 to 40, somewhere in that zone.

14 CHAIRMAN CARR: Of a 1.2 million or 400,000?

15 MR. BAGGETT: Prior to contacting the
16 general licensees in '82 and '83 and '84, we received
17 maybe 10 or 12 a year. That's increased just due to
18 the degree of regulatory awareness. They are now
19 assigning some responsibility -- some are on this
20 annual reporting.

21 COMMISSIONER CURTISS: Sounds like it's ten
22 percent or less.

23 MR. BERNERO: I don't think we could do a
24 successful material balance, based on our --

25 COMMISSIONER ROBERTS: I think not.

1 CHAIRMAN CARR: Well, I'm concerned about--
2 I don't know if these things are sold through the
3 mail. I'm sure they're not just necessarily an over-
4 the-counter purchase. But I'm concerned that the
5 specific licensee, when he makes the transfer to
6 somebody and he tells us who that was, he also tells
7 us, I assume, the name of the "responsible
8 individual." Right? That's the way I read it.

9 MR. AUSTIN: Well, it could be a purchasing
10 agent. We would recommend specifying it be a
11 responsible individual.

12 COMMISSIONER ROBERTS: By name or by title?

13 MR. AUSTIN: At least by title.

14 CHAIRMAN CARR: But I don't have a warm
15 feeling that unless we require the guy immediately on
16 receipt to acknowledge to us that he has received it
17 and understands his responsibilities -- it's kind of
18 like for a while the FCC required you to report when
19 you bought yourself a CB radio and it got too much to
20 handle. But at least you were required to report that
21 you had one and you had a frequency.

22 MR. BERNERO: And that's a very good
23 example, because that at least told the purchaser that
24 there was a regulatory authority and they had an
25 identify and there was some attempt at control.

1 I think we're starting to draft the control
2 rulemaking here, but these are the very issues that
3 we're trying to study so that we can see whether by
4 the initial sales representative giving the
5 information to the purchaser, and then perhaps a
6 separate but coincident purchaser initial report to
7 the NRC, followed by an annual reminder report that
8 requires a certain amount of different or interpretive
9 thinking. In other words, not simply, "Yes, I bought
10 a device from the XYZ Company," but "I bought a device
11 and I know it's radioactive and I know this and this
12 and that and that."

13 Our objective is to put into the corporate
14 memory, "Yes, you have a device. There are certain
15 obligations that go with it, and we're going to keep
16 track of it. We'll be in touch with you on an annual
17 basis and we need to know about changes or transfers
18 of control.

19 CHAIRMAN CARR: And, as I say, even in their
20 brochures and their catalogues, if these things are
21 listed in a catalogue --

22 MR. BERNERO: They are.

23 CHAIRMAN CARR: -- there'd be a little note
24 there warning this requires some kind of a -- this
25 contains radioactive material and requires

1 notification when you own it.

2 COMMISSIONER CURTISS: Just looking at the
3 numbers here, with 400,000 of these people licensed by
4 the NRC, we may get more letters than we got on the
5 emergency planning rulemaking as a result of a process
6 that looks at the general licensee.

7 I wonder if there's not some merit to,
8 because of those numbers, looking to the specific
9 licensee, of which we have what, 80, 70?

10 CHAIRMAN CARR: 130 total.

11 COMMISSIONER CURTISS: 130 total, about --

12 CHAIRMAN CARR: States and us.

13 MR. BERNERO: A much more manageable set --

14 COMMISSIONER CURTISS: -- into the specific
15 licensee and telling them, "We're interested in having
16 you track where the devices go," as they go from
17 general licensee to general licensee and then auditing
18 the specific licensee on a regular basis to ensure
19 that they've set up a mechanism to do that. It almost
20 boggles my mind that we've got 400,000 people out
21 there, 400,000 licenses here and I take it 800,000
22 that we'd like to have a similar process for at the
23 agreement state level, it may be a matter of
24 compatibility for them, where we're going to seek to
25 track 1.2 million devices and every transfer of those.

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1 MR. BERNERO: Yes.

2 COMMISSIONER CURTISS: Is that a burden we
3 ought to take on or that the specific licensee ought
4 to take on given the interest that it has economically
5 in selling those?

6 MR. BERNERO: It's only perhaps one order of
7 magnitude smaller, but the number of licensees is
8 going to be on the order of -- an order of magnitude
9 less than the number of devices, so that our
10 communications would be on average with somebody who's
11 got perhaps ten devices.

12 But still, it's an intimidating or daunting
13 number of communications. But again, we're going into
14 a rulemaking draft. But if we go to the manufacturer
15 or distributor, it puts us one step removed and once
16 again we're -- but there's a real resource advantage.

17 When we went through 3M, I used to shudder
18 at all of the mailings. The cost of the mailing, I
19 forget the sum, but it was in the thousands of
20 dollars, many thousands of dollars, just to send a
21 copy of one of those orders to the general licensees.
22 We did that all through 3M. It was very costly.

23 CHAIRMAN CARR: You're convincing me that we
24 ought to track what's important for public health and
25 safety and we ought to forget the rest of it.

1 MR. BERNERO: But this is the cost
2 effectiveness of how we track it.

3 CHAIRMAN CARR: Well, but we don't have to
4 track all 400,000 of those.

5 COMMISSIONER CURTISS: If the ones that are
6 issued to the general licensee are as we've defined
7 them, inherently safe, there's nothing that you can do
8 or not as much that you can do with the device if you
9 read the instructions. I guess I wonder, does it make
10 sense on the use problem to draw a distinction between
11 those maybe over a curie and those under a curie. It
12 looks to me, just in rough numbers, like we've got
13 about 15 percent of all the devices that exceed one
14 curie.

15 MR. BERNERO: Now I would ask you to pause.
16 The ones where the inherent safety is enough that you
17 don't have to track them, those we exempt, the smoke
18 detectors and wrist watches and things like that.
19 Those are exempt from regulation. The reason --

20 CHAIRMAN CARR: If you took just the greater
21 than Class C and said, "That's a problem we can deal
22 with," that limits to 20 plus thousand, more or less,
23 instead of 400,000.

24 MR. BERNERO: That might be a segmentation
25 that can have some merit. But again, that's the --

1 COMMISSIONER CURTISS: That's the disposal
2 question that Commissioner Rogers raised.

3 CHAIRMAN CARR: Well, no, that's also the
4 high --

5 MR. TAYLOR: The public health and safety
6 issue usually comes up when these devices are
7 mistreated, smashed, broken.

8 CHAIRMAN CARR: It only comes up when you're
9 worried about putting material in a Coca-Cola bottle.

10 MR. TAYLOR: Yes, or released, but in some
11 way where the material gets out of the encapsulation.
12 That's the manufacturer's object, is to contain it.

13 COMMISSIONER CURTISS: But I take it you've
14 got a number of devices that are not greater than
15 Class C that are in excess of one curie that might
16 pose an operational concern that you'd like to track
17 to a greater degree than less than a curie.

18 MR. TAYLOR: We'd have to do those things.

19 MR. BERNERO: Yes. I don't recall that as a
20 category.

21 COMMISSIONER CURTISS: Just look at your
22 chart in the back of your enclosure 1.

23 CHAIRMAN CARR: But what I'm saying is
24 there's a limited number that fit the category you're
25 really worried about.

1 MR. AUSTIN: Right, correct. They're a
2 limited number, limited designs, limited materials and
3 limited uses. That is what would be explored in a
4 rulemaking that you would recommend that would better
5 define the criteria under which any device could be
6 within the general license program. Now --

7 COMMISSIONER CURTISS: It seems to me just
8 looking at the numbers, if you took the areas that
9 you're concerned about, the greater than Class C
10 devices are the ones that you're concerned about from
11 from the standpoint of disposal. If that's the
12 concern, it would seem to me to be a fairly simple
13 thing to say to the specific licensees, "You have to
14 ensure that you get those back and that you dispose of
15 them." And there are what, did we say 22,000?

16 CHAIRMAN CARR: Well, I'm sure that number
17 will be refined.

18 COMMISSIONER CURTISS: That cures that
19 problem and you're left with are there devices out
20 there in addition to those that you're concerned about
21 during operation. Just looking at the chart, I'm just
22 adding up the ones that have americium 241 in them and
23 it comes out to about a total of, oh, I think 180,000
24 self-luminous exit signs. Ones that are in excess of
25 one curie, it seems to me, are the ones that we ought

1 to focus on tracking during the operational life and
2 that could be done, I think, most efficiently through
3 the specific licensee, through the manufacturer. Tell
4 us where they are.

5 MR. BERNERO: We're going to have to sort
6 out the sets and sort out in a rulemaking the
7 appropriate segregation, reporting, possibly even
8 going -- I'd like to caution about -- we got into the
9 multi-curie. It's an old rule of thumb, if it's a
10 curie or more, it's something to worry about. But
11 there are some curies I worry about a lot more than
12 other curies. And so, it's a tough thing to draw a
13 line, a clear line --

14 CHAIRMAN CARR: I can tell you right now, if
15 you're going to track exit signs, you're never going
16 to catch up with the problem.

17 MR. BERNERO: Yes. That's some of the
18 curies I don't worry so much about.

19 MR. AUSTIN: Also for enhancing the control
20 over these devices, as I mentioned previously, we
21 would require the manufacturer to inform the general
22 licensee of the disposal cost because they could be so
23 great and for some of these smaller companies they may
24 not be able to afford it.

25 And the last tic on viewgraph 9 is what we

1 have just been discussing, in what way might we limit
2 devices coming under the general license program. We
3 would explore that in the rulemaking.

4 (Slide) To enhance the quality of the
5 devices, we would recommend having third party testing
6 of the devices. Not necessarily all of them, but
7 decide which ones would be required to be subjected to
8 third party testing in a rulemaking. Again, we think
9 this would be -- should be an independent test. Staff
10 now has initiated its own independent testing of
11 certain devices, some tritium exit signs now, and we
12 will be expanding that program. But again, believe
13 that the vendors should be required to have a third
14 party carry out those kinds of tests.

15 The primary benefit of that test is that we
16 would have better confirmation of the adequacy of the
17 design. Now we look at a sheet of paper, a paper
18 design, and have to reach a judgment as to its
19 adequacy.

20 The second part of enhancing the quality of
21 the designs is to have a performance oriented quality
22 assurance rule or a reg guide. It could possibly be
23 described in a regulatory guide. But the main message
24 is in some way make sure that there is an adequate
25 quality assurance program. Now, there is a little NRC

1 oversight of and requirements on manufacturers'
2 quality assurance programs.

3 We've discussed several times here the
4 greater than Class C waste. That issue exists whether
5 it's a generally licensed device or a specifically
6 licensed device and we would propose to address that
7 when we respond to a previous staff requirements
8 memorandum to get back to you late this year.

9 CHAIRMAN CARR: What do you mean address it?

10 MR. AUSTIN: I believe you have asked for us
11 to gain more data on what is the problem with respect
12 to surplus greater than Class C waste. We are in the
13 process of that and we owe you a response back I think
14 it's in December of '89.

15 MR. BERNERO: And how we are dealing with
16 the outstanding problem of that, which includes the
17 interaction with DOE. I don't know if you've heard
18 it. I've just heard, by word of mouth yesterday, that
19 DOE has released their plan for greater than Class C
20 waste. I haven't seen it and I'm certainly interested
21 in seeing it. I've seen drafts of it.

22 COMMISSIONER CURTISS: The things that I've
23 read indicate that DOE is prepared to take on an
24 interim basis greater than Class C waste in 1990. If
25 that's FY'90, that's about two weeks away. And I

1 guess the concerns that I have that the General
2 Counsel raised in his June 30th memo about how you
3 track the material that goes into the DOE facility
4 that has to wind up in a licensed disposal facility,
5 it seems to me need to be addressed. I encourage you
6 to do that in that paper.

7 It may be worth taking a look at whether DOE
8 plans on taking this waste from our licensees two
9 weeks from now or making their facilities available,
10 if that's an FY'90 plan that they have. If that's the
11 case, it does seem to me that it's also worthwhile to
12 tell the licensees in some way or another that greater
13 than Class C waste that goes to a DOE facility has to
14 wind up in a licensed disposal facility and somehow
15 putting them on notice that turning the material over
16 to DOE isn't the end of the regulatory chain for us.
17 It's not clear to me we've done that yet.

18 MR. BERNERO: No. We have been discussing
19 that with DOE and the DOE people just briefed the
20 Advisory Committee on Nuclear Waste about their plan,
21 oh, about two weeks ago or so. The plan has been in
22 existence for some time and it was awaiting Sectary
23 Watkins' review. Apparently, if the news report is
24 correct, the approval is there and I'm looking forward
25 to sitting down with DOE very soon to sort out these

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1 very issues because we have discussed them with them
2 intensively the whole idea of tracking the material,
3 the prices or costs to be collected and how to
4 separate an emergency possession from a routine
5 possession because we have these well loggers going
6 out of business and going bankrupt and things like
7 that.

8 CHAIRMAN CARR: Well, but I don't -- if when
9 you say you're going to address it in consonance with
10 this, you mean you're just going to add these numbers
11 in?

12 MR. BERNERO: No, no. We have to establish
13 a mechanism whereby licensees have greater than Class
14 C waste to dispose of and have a way to dispose of it
15 that is an orderly --

16 CHAIRMAN CARR: When you take care of that
17 problem, you've taken care of this one.

18 MR. BERNERO: No, not necessarily because I
19 would still have the concern that a general licensee,
20 even though the general licensee has a way to dispose,
21 a reasonable way to dispose of greater than Class C
22 waste, may not do so. They may throw it in the
23 landfill or something.

24 CHAIRMAN CARR: So why not address that
25 issue? You don't address that by solving the problem

1 of where you're going to put Class C waste.

2 MR. BERNERO: No, that I address within
3 the --

4 CHAIRMAN CARR: But I'm concerned that
5 you're trying to wrap it into the other paper and I
6 don't want it wrapped in.

7 MR. BERNERO: No. Oh, no, no. No. We're
8 not going to deal with the licensee control of the
9 device to make sure it reaches the proper destiny in
10 greater than Class C land. No. As long as there is a
11 generally licensed device that is of that category of
12 waste in the general license arena, we will deal with
13 the issue of whether or not that can only be leased,
14 the vendor takes it back or whatever control mechanism
15 is appropriate and then the disposal mechanism is the
16 separate issues and that's --

17 COMMISSIONER CURTISS: A related question.

18 CHAIRMAN CARR: Having said all that, what
19 do you mean by this paragraph here?

20 MR. AUSTIN: The former. That is that the
21 matter of actually disposing of the greater than Class
22 C waste would be addressed and hopefully resolved in
23 the paper that is due to you the end of this year.

24 CHAIRMAN CARR: Okay.

25 MR. AUSTIN: The issue of control, I

1 believe, ought to be addressed in the rulemaking
2 dealing with criteria of devices that should be
3 allowed to come under the general license.

4 CHAIRMAN CARR: So you're going to address
5 it in two things?

6 MR. AUSTIN: Yes.

7 MR. BERNERO: Right.

8 MR. AUSTIN: Two parts.

9 CHAIRMAN CARR: Put a third bullet on that
10 one. All right.

11 MR. AUSTIN: The fourth initiative staff is
12 undertaking has to do with the quality of the
13 licensing reviews of generally licensed devices.
14 Currently, all of the 29 agreement states are
15 authorized to perform sealed source device reviews.
16 This could lead to varied interpretations, the lack of
17 uniformity. NMSS would like to, in achieving better
18 assurance of consistency and uniformity, take a harder
19 look at the sealed source and device registry sheets
20 that the agreement states submit to us. Now they come
21 in and they go into a folder. We can see an advantage
22 of taking them and looking at them for completeness,
23 compliance with regulations, adequacy of review to
24 again provide better assurance that devices that are
25 being sold country-wide, foreign countries --

1 CHAIRMAN CARR: But the applicant is a
2 specific licensee.

3 MR. AUSTIN: Of the agreement state.

4 CHAIRMAN CARR: He is a specific licensee
5 and when he comes in to us or to them, he comes in to
6 license a specific piece of material under a general
7 license.

8 MR. AUSTIN: He gets a specific license and
9 what's called a G license. The G license authorizes
10 him to distribute to people who do not have specific
11 licenses.

12 CHAIRMAN CARR: But not anything he wants
13 to, only particular things.

14 MR. AUSTIN: Only things approved.

15 CHAIRMAN CARR: And forget how the states do
16 it. How do we do it? How do we handle those guys
17 that come in? What kind of tests do we do? What do
18 we require of the guy? Are you saying the states
19 aren't compatible?

20 COMMISSIONER ROBERTS: I think you're saying
21 they don't know.

22 CHAIRMAN CARR: But they know they require
23 the states to be compatible.

24 MR. TAYLOR: I think John's point is to look
25 at the devices that have been licensed by specific

1 license in the agreement states and be sure that the
2 collective knowledge is gathered together. So, if we
3 see a device that we may have question with, that we'd
4 appropriately convey that and discuss it. They may
5 even be doing something better.

6 CHAIRMAN CARR: Oh, you mean for those
7 states that are using a specific instead of a general
8 license for the same device?

9 MR. AUSTIN: Yes. The manufacturer has two
10 licenses that are specific to them. They have a
11 license that authorizes them to possess and use
12 material at their site. Then, as a separate matter,
13 we issue what's called a G license. It's essentially
14 the same thing with a G added to it, which -- the only
15 effect of that is that we tell that licensee, "You are
16 authorized to distribute to people who do not have a
17 license."

18 CHAIRMAN CARR: But if he makes more than
19 one product, does he have more than one G license?

20 MR. AUSTIN: No. That one G license can
21 cover thousands of products, but once he sells it to
22 that --

23 CHAIRMAN CARR: No, no, I don't mean
24 thousands of the same product. I mean two different
25 products.

1 MR. BERNERO: No. The point of the matter
2 is that orange box down on the end of the table, he
3 has a specific license because he has to build those
4 things for his business and it's got --

5 CHAIRMAN CARR: It's got radioactive
6 material, he manufactures something.

7 MR. BERNERO: But then he is licensed to
8 distribute that device and the specifics of that
9 device, which is authorized for general --

10 CHAIRMAN CARR: On a G license.

11 MR. BERNERO: Yes. And that's what we would
12 like to be sure -- and we look at state exercises in
13 that as well as our own for technical and regulatory
14 consistency.

15 CHAIRMAN CARR: But I assume we do that when
16 we inspect the state's program.

17 MR. BERNERO: Well, I'm not sure we do
18 enough of it. There's room for more. We have had
19 substantial dialogue on this and I think there's room
20 for more --

21 CHAIRMAN CARR: Let's go back to my second
22 question. If the guy that makes the orange box also
23 makes the exit sign, has he got another G license?

24 MR. AUSTIN: Yes, separate.

25 MR. BERNERO: For that device. For that

1 device, the exit sign.

2 MR. BAGGETT: He would have one piece of
3 paper and item A on his license to sell would say this
4 orange one and item B would say this particular one
5 here and there would be --

6 CHAIRMAN CARR: So we add to his G license
7 as he comes in for another product.

8 MR. AUSTIN: Right.

9 CHAIRMAN CARR: Any time he sends us a
10 product that he wants to add to his license, what kind
11 of testing do we require?

12 MR. BAGGETT: The regulations require that
13 he submit testing to demonstrate to us that it will
14 survive the conditions of use. This one would be a
15 lot of testing, say dropping it from 30 feet, and this
16 one may not be --

17 CHAIRMAN CARR: But that's spelled out in
18 our regulations.

19 MR. BAGGETT: It says that you will provide,
20 right.

21 MR. BERNERO: Excuse me. I don't think it's
22 spelled out in our regulations. It's spelled out in
23 our testing licensing review activity, our specific
24 review. I don't recall the regulations setting down
25 like a type B package or anything like that set of

1 tests.

2 CHAIRMAN CARR: How does he know what to
3 submit to us when he sends us his piece or his data
4 for his exit sign?

5 MR. BAGGETT: We have some regulatory guides
6 that explain what we're looking for in a product
7 design and references some of the ANSI standards to
8 give them an idea of types of testing that we're
9 looking for.

10 MR. BERNERO: And he has performance
11 objectives that are in the regulations about doses
12 under normal conditions or accident conditions.

13 CHAIRMAN CARR: And I assume that's a matter
14 of state compatibility. So, I'm trying to go back and
15 find out what it is you're going to -- what you're
16 worried about in the licensing review area. The fact
17 that we're not doing it?

18 MR. AUSTIN: That we need --

19 CHAIRMAN CARR: Or the fact that we're not
20 doing it well or the fact that we don't require enough
21 documentation?

22 MR. AUSTIN: The sealed source in device
23 reviews can become rather complicated. Sometimes
24 you're dealing with rather simple things, others get
25 rather complicated. It takes a certain critical mass

1 of individuals to understand what all they need to
2 look into of a design to determine its adequacy for
3 general distribution. It's not obvious that all
4 agreement states have that critical mass. Maybe they
5 do, maybe they don't.

6 CHAIRMAN CARR: Do we have it?

7 MR. AUSTIN: We have it.

8 CHAIRMAN CARR: Do we use it?

9 MR. AUSTIN: Yes, sir.

10 CHAIRMAN CARR: Okay. So, it's a matter of
11 inspecting the state programs to make sure they
12 comply.

13 MR. AUSTIN: Yes, and the regulations, in my
14 view, are not complete. There's room for
15 interpretation, how far do you go, you push harder in
16 this case but not in that. The thought here is that
17 because this involves worldwide distribution of
18 radioactive devices, should not a federal agency have
19 a firm understanding of the adequacy of the reviews?
20 See, we never turned over to the agreement states the
21 authority to issue E licenses, exempt distribution.
22 NRC, NMSS performs those reviews because of the
23 national implications of it. Here, is there not a
24 middle ground where we receive their product, their
25 engineering evaluation, their safety evaluation

1 report, the design and say, "Would we have approved
2 that? Does it meet what we think the requirements
3 are?"

4 CHAIRMAN CARR: Well, that's why they send
5 it to us, I assume.

6 MR. AUSTIN: They only send us the
7 registration sheet for the device such that it is in a
8 central location, so that if someone else looks to
9 manufacture that device, they can rely on that sheet.
10 But in terms of evaluation of the adequacy of that
11 sheet and conditions, we do very little of that now.

12 CHAIRMAN CARR: Well, from talking to the
13 states' guys who talk to me, they lead me to believe
14 they do a better job of it than I do.

15 MR. AUSTIN: In some cases, that may be
16 true. In other cases, I'm not sure it's true.

17 CHAIRMAN CARR: Okay. Let's proceed.

18 MR. BERNERO: Now, at this point, let me
19 take over.

20 (Slide) Could I have slide 11, please?

21 In one editorial version of this paper, we
22 had a table that's a little more detailed. It might
23 be a useful supplement to you here. Basically, we're
24 talking about the two budget years, FY'90 and FY'91,
25 in harder terms than we talk about the out years. If

1 we're going to do some of this activity, what are the
2 resource implications? If you look at this more
3 detailed table that I gave you a photocopy of, it has
4 two basic categories, the FTE required for these
5 initiatives and the FTE already allocated. Obviously,
6 FY'90 and '91 are the harder numbers and FY'92 to '94
7 is prospective or speculative. In the already
8 allocated number, it's that out year budgeting process
9 that we have.

10 In essence, this should give you a scale of
11 the overall activity, the number of FTEs involved in
12 all of the categories. In FY'90, we're going into
13 this tracking maintenance and developing the reporting
14 requirements and the follow-up inspection activity and
15 the important thing to note is this is an information
16 gathering phase. We should be a whole lot smarter
17 about the situation a year from now than we are right
18 now.

19 Our prospects for how big is the problem or
20 how small is the problem can change rather
21 significantly because this early activity is the
22 information gathering where you find out are they
23 really in a disorder and scattering these things to
24 the four winds or is it just that we didn't have
25 sufficient information to see?

1 So, if you look at the resources allocated,
2 we've got it broken down into the five categories of
3 regulatory activity and in a footnote of this table
4 and in the Commission paper we spoke of it. The
5 Office of Research has a one and a half FTE per year
6 underpinning for us to support this rulemaking
7 activity. So that at last mentally add that to the
8 FTE figures you're looking at.

9 Now, the things I would invite your
10 attention to in looking at the resources are, one, in
11 the current years this state oversight -- it's the
12 fourth item in the table, expand oversight of
13 agreement state program and provide more technical
14 assistance to states. We do not have two additional
15 FTE allocated there but we've got an agreement with
16 our colleagues in state programs that we're going to
17 try as resources are available from one source or
18 another to ease into that in the years prior to our
19 ability to actually budget for that. We consider that
20 just below the line in priority and therefore we
21 haven't actually allocated those FTE.

22 If you'll look at the column for FY'92 and
23 '94, the projections of the tracking for an expanded
24 annual survey of four FTE per year is probably a
25 realistic one. We think that will be a realistic

1 expenditure. But if you look down to the third item,
2 review vendor QA programs, increase licensing and
3 inspection effort, we're foreseeing one FTE to get
4 going on that in the requirements end, and perhaps
5 four FTE if we follow a pattern such as we're talking
6 about in the medical QA where we're going to go out
7 and verify the implementation of the device QA
8 programs. That's probably a fairly realistic number.

9 The certain devices to be specifically
10 licensed, the thing on the bottom, that's up in the
11 air. That could be -- if we came to a regulatory
12 conclusion through rulemaking that a large fraction of
13 these devices should be done by specific licensing,
14 that could be very resource intensive. On the other
15 hand, if we find that there is an orderly way to deal
16 with them in the general license arena, then that
17 number of resources would be much, much smaller.

18 So, I just want to give you -- this is
19 obviously not a budget briefing, but I want to give
20 you the flavor of the information gathering phase
21 being such that in the out years, the necessary
22 resources to pursue the proper general license program
23 remain to be established firmly. We will, of course,
24 propose, as the information comes in, propose in our
25 future budgets.

1 (Slide) May I have slide 12, please?

2 CHAIRMAN CARR: Before you leave that one,
3 you're telling me that you've got seven people
4 allocated through '94, if I add up the last column,
5 and you need somewhere between 11 and 16 more by '94
6 if I add up the last column in the required.

7 MR. BERNERO: Yes. But that's why I wanted
8 to give you the -- in the last column of the FTE
9 required, the four for item number one is probably a
10 fairly good number. The four for the item number
11 three, is probably good, but that bottom one is mushy.

12 CHAIRMAN CARR: Well, but --

13 MR. BERNERO: And it dominates.

14 CHAIRMAN CARR: -- 11 to 16 is not very
15 mushy. I mean that's not very accurate, shall we say,
16 anyway. But what you're telling me is we need to
17 throw in 11 to 16 more FTE to take care of something
18 you've already said you don't think is a threat to
19 public health and safety, but you don't have the data.

20 MR. BERNERO: I'd just go back to the
21 proposal that in the current budget years we're
22 putting in the control activities that will establish
23 what we have and we could end up with the low end of
24 that scale which would be, I think, the necessary
25 discipline for a general license program to ensure the

1 public health and safety. And the high end of that
2 resource program would be associated with discovering
3 enough problems that we have to withdraw items from
4 the general license program and put them in the
5 specific license program which is more costly.

6 CHAIRMAN CARR: All right. Let's go ahead.

7 MR. BERNERO: Have slide 12.

8 Let me just summarize our conclusions.
9 Recall what was in the paper and what John's briefing
10 covered. We've come to the conclusion that we should
11 continue the general license program but give
12 increased attention to it. We don't have enough
13 information to say with adequate confidence that
14 everything is in excellent condition or excellent
15 shape. There are just too many unknowns, too many
16 doubts.

17 So, we have these initiatives that we've
18 spelled out in the paper. They have already started
19 and they will proceed and as each rulemaking or
20 whatever comes to a head, we'll be coming to you with
21 them. They're on the two fronts, basically and
22 initially to improve controls, to get a better handle
23 on everything that's going on, who has them, do they
24 know they have them, what happens to them, and
25 secondly, to enhance their quality. And so you'll see

1 the priority in our initiatives is first and foremost
2 to the improvement of controls and of course getting
3 the information for that, and then secondly enhance
4 the quality of the devices that are under control.

5 So, that concludes our presentation.

6 CHAIRMAN CARR: Questions?

7 Commissioner Rogers?

8 COMMISSIONER ROGERS: No, I don't think so.

9 CHAIRMAN CARR: Commissioner Curtiss?

10 COMMISSIONER CURTISS: Nope.

11 CHAIRMAN CARR: Well, I've got all kinds of
12 problems with this thing. The first one is it looks
13 like we've been doing nothing for three years since
14 they reported out their study that said we ought to
15 get on with it. When I get the briefing here today, I
16 kind of get the feeling that there's still not
17 something I can get my arms around and say, "We're
18 going to have that done by this time."

19 When I look at your table, I'm not sure that
20 we don't already have the data we need. Somebody can
21 set down and look at those sources and make a little
22 bit of a study of what we know about how they're put
1 together and decide whether there is a real threat to
2 the public health and safety. I don't think we have
3 to do a lot more than that.

1 It wouldn't take a lot of analysis to sit
2 down and look at what the source is, how it's
3 encapsulated, what they use it for, and make a
4 decision on which of these are really going to be a
5 problem, either from disposal or from misuse or
6 whatever. And after they've got that, then we can act
7 on that. If we're worried about disposal, we make
8 whatever is necessary to make sure that it happens
9 that way. If there are some in this list that aren't
10 worth worrying about, that are BRC, then let's quit
11 worrying about those.

12 I don't understand, I guess, why it's a two
13 or three year more problem when we've had three years
14 to work on it. The recommendation's there. Everybody
15 recognizes it's clear. The states are bitching. We
16 recognize that the problem -- and it seems to me we've
17 got a better handle on the problem than you left me
18 with the idea that we do. That may be mistaken on my
19 part, but I stand ready to be corrected.

20 But I think it seems to me that the risk to
21 the public is what we ought to base all this on. And
22 once you decide that, since we know what we're dealing
23 with here, the way to figure that out is pretty
24 straightforward.

25 The question that we don't know is what's

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1 out there, it seems to me. And you say you're working
2 on that and you're going to get a handle on that
3 within the next year, and I'm glad to hear that. But
4 I think personally I'd like to see the staff provide
5 the Commission within a reasonable amount of time--
6 which seems to me three or four months -- an analysis
7 of the potential health and safety aspects of these
8 devices and identify those that you think greater
9 regulatory control is required on, and give us some
10 recommendations so we can do something.

11 I get the impression here we're going to
12 launch off into a long study of the problem and then
13 some day down the pike we'll come up with some
14 solution to it, maybe, if we've got enough manpower
15 and money, and that leaves me a very warm feeling.

16 MR. BERNERO: Mr. Chairman, I think that I
17 can say this, that in a short time span of the order
18 of three to four months we can give you an analysis of
19 the sources in that table and I can forecast the
20 degree of report that we can make. I would expect
21 that virtually none of them would fall into BRC, or
22 almost none. I doubt very much that you'll find any
23 of those sources --

24 CHAIRMAN CARR: Even if we get the BRC rule
25 out?

1 MR. BERNERO: Even with the BRC policy out,
2 I think that just by the simple fact that they are
3 designed to meet accident release and normal exposure
4 standards that are in the regulations and that are
5 substantially different from what one associates with
6 BRC, I don't think any of those are going to fall into
7 BRC land.

8 CHAIRMAN CARR: All right.

9 MR. BERNERO: I think we will be able to
10 identify, though, a category -- I'll call them the
11 "worry set," or the "troublesome set," that are up at
12 a range that could --

13 CHAIRMAN CARR: Something a lot less than
14 400,000.

15 MR. BERNERO: Yes. But a small set that are
16 in a category that might be potentially or actually
17 ineligible for general licensing, that in a better
18 world you would have requirements that succinctly
19 exclude certain devices.

20 Now in rule of thumb, we have referred to
21 those as the greater than one curie devices, but
22 that's too simple a definition. You know, it's not
23 adequate. But I think we could identify that category
24 of sources in this list that fall into the arena that
25 maybe these things shouldn't be generally licensed

1 devices and how can we define them out of the
2 universe.

3 But I would say I would expect that that
4 analysis would tell you, okay, you've reduced the list
5 a little bit if you just arbitrarily rule out the
6 troublemakers or worry devices.

7 CHAIRMAN CARR: Probably an order of
8 magnitude.

9 MR. BERNERO: I doubt it. I doubt it very
10 much. I think you'll still have a very large number
11 of pavement gauges, moisture density devices, and coal
12 slurry devices.

13 CHAIRMAN CARR: Because only of their
14 source?

15 MR. BERNERO: That you will have --

16 CHAIRMAN CARR: I want to know what the
17 threat to the public is.

18 MR. BERNERO: Yes. If it gets out --

19 CHAIRMAN CARR: If it's properly
20 encapsulated, am I worried about it?

21 MR. BERNERO: Well, as we said in the paper,
22 the threat to the public, we don't know of anyone
23 who's ever been killed by one of these sources the way
24 they've been killed by a teletherapy source or by a
25 radiography source. But they can get a significant

1 exposure if the source is somehow drilled through or
2 broken up.

3 CHAIRMAN CARR: But you can also take a look
4 and see how it's used and decide what the probability
5 of that is.

6 MR. BERNERO: Oh, we do. In fact, the
7 regulations say what it has to be in order to qualify.

8 CHAIRMAN CARR: And I would assume we
9 already would have done that or we wouldn't have it in
10 the box as a generally licensed item.

11 MR. BERNERO: Yes. We establish in the
12 regulations the requirements for the normal exposure
13 and for the accident exposure potential for that
14 device in order to qualify for the general license.

15 CHAIRMAN CARR: And what we're worried about
16 now is have we done that right and have we made a
17 mistake in some of those.

18 MR. BERNERO: Yes.

19 CHAIRMAN CARR: And all I'm saying is,
20 you've got the data, why don't we look and decide
21 whether we've made a mistake? And those few items we
22 might have made a mistake with, come to us and we'll
23 change it.

24 MR. BERNERO: You're talking about what
25 amounts to a rereview of --

1 CHAIRMAN CARR: That's what you're talking
2 about, I think. You're saying that we've got some out
3 there generally licensed that we shouldn't have
4 generally licensed.

5 MR. AUSTIN: The devices that are out there
6 comply with 32.51 and 31.5. If we went to a -- in
7 essence, what you're saying is should we revoke the G
8 license of one of the vendors for those.

9 CHAIRMAN CARR: Or something.

10 MR. AUSTIN: And the licensee can say, "I am
11 in compliance with all of your regulations. On what
12 basis are you revoking my G license?"

13 Rather, you could start a rulemaking that
14 would allow the vendors a chance to comment on it,
15 that says, "We will use this thought process in
16 deciding whether or not a device should be generally
17 licensed or specifically licensed." And it's going to
18 be backfit. And you could go through that
19 administrative procedure.

20 MR. BERNERO: John, wait a minute. I think
21 the essence -- there are two reasons why a device on
22 that list might indeed come off that list.

23 One reason is, in retrospect when I look at
24 it I think the review that authorized its distribution
25 was flawed, that it doesn't really meet the criteria

1 in the regulations. That's one reason. And that is
2 an extensive reanalysis of the docket and accident
3 calculations, models, whatever.

4 There is another reason, and that's what I
5 was referring to by the troublemakers. It is the ones
6 that do meet the nominal criteria, but are close
7 enough to the upper end of it or --

8 CHAIRMAN CARR: Or that common sense says,
9 "Hey, we shouldn't have done that."

10 MR. BERNERO: -- constitute a sufficient
11 uncertainty that we would say, "In order to exclude
12 these, I'm going to have to change the rules." I'm
13 going to have to redefine the criteria to say "Here
14 are the criteria you meet, and in addition you meet
15 some other criteria or set of criteria in order to
16 include or exclude appropriate sets."

17 So I was talking about the ones that would
18 presumably meet the criteria, but would be at the
19 borderline. And I think what you're talking about is
20 an audit of the review process for whatever number of
21 devices it is.

22 CHAIRMAN CARR: What I'm talking about is,
23 if we've got generally licensed items out there that
24 are a threat to the public health and safety, either
25 from a disposal operation or improper disposal or from

1 a misuse, and we know what those are, then those are
2 the ones we ought to focus on. And it seems to me
3 we've got enough data to know which those are.

4 MR. BERNERO: We certainly know the greater
5 than Class C, and we are focusing on those. And I
6 think that in this time period we can sharpen the
7 focus on the ones that are in either category,
8 possibly flawed safety evaluation or within the
9 expected safety evaluation criteria, but so close to
10 be uncomfortable.

11 CHAIRMAN CARR: Well, we can make a
12 judgement on that.

13 MR. BERNERO: Yes, we can make that
14 judgement. I think we can do that.

15 CHAIRMAN CARR: And it's important, of
16 course, to remember we've got to consider the state's
17 perspective in all this, which you've been doing, I
18 think.

19 Any comments from my fellow Commissioners
20 additionally?

21 COMMISSIONER ROGERS: Well, just the -- that
22 additional 11 to 16 people per year looks like a
23 pretty substantial commitment for us to make, and I
24 think we better be darn sure we know what we're doing
25 and what we're getting for it, because it's a big

1 price tag compared to all the other things that we
2 have to do that are on our plate.

3 MR. BERNERO: That's the very reason we're
4 laying it on the table, not in budget space, but in
5 programmatic forecast.

6 MR. TAYLOR: You haven't made a budget.

7 MR. BERNERO: No, no.

8 CHAIRMAN CARR: Well, as I said, I'm glad to
9 see we're getting on with it. It seems to me we could
10 have done -- we're late in doing our work.

11 COMMISSIONER ROGERS: I just think that some
12 of the points the Chairman has been making suggest
13 some ways that you might reanalyze this whole thing or
14 look at it in a little different perspective, because
15 I can't add anything to what he said. I haven't
16 really quite feel I've got a grasp of this thing yet,
17 but I have a sense that somehow we're going by the
18 numbers in some way and what we have to do is not
19 count up numbers, but really go back and reanalyze the
20 situations. And I think that's what the Chairman
21 seems to be suggesting to me, and I'd like to
22 reinforce that.

23 CHAIRMAN CARR: I think the thing it comes
24 down to is there's some of this stuff should be
25 specifically licensed or not, and that's what we're

1 going to arrive at. But I'm convinced that there's
2 not reason to do 400,000 specific licenses.

3 MR. TAYLOR: I agree.

4 CHAIRMAN CARR: I would be surprised if
5 there was reason to do 10,000 specific licenses out of
6 those things. It ought to be some where down -- I
7 mean, that should bound it, in my opinion, but I may
8 be wrong. But we need a good argument if we're going
9 to say more than that.

10 Any other comments? If not, we stand
11 adjourned.

12 (Whereupon, at 11:40 a.m., the above-
13 entitled matter was concluded.)

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CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting
of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON STUDY OF ADEQUACY OF REGULATORY
OVERSIGHT OF MATERIALS UNDER A GENERAL LICENSE

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: SEPTEMBER 21, 1989

were transcribed by me. I further certify that said transcription
is accurate and complete, to the best of my ability, and that the
transcript is a true and accurate record of the foregoing events.



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GENERAL LICENSE PROGRAM
RE-EVALUATION

September 21, 1989

John H. Austin, NMSS

Contact: John H. Austin
Phone: 492-0689

GENERAL LICENSE PROGRAM RE-EVALUATION

- ° GENERAL LICENSE PROGRAM
- ° PROBLEMS
- ° QUESTIONS BEING ADDRESSED
- ° PLANS FOR IMPROVING AND
UPDATING PROGRAM
- ° STAFF INITIATIVES AND
RESOURCES

DEGREES OF REGULATORY CONTROL

- ° SPECIFIC LICENSE
 - RADIATION PROTECTION PRINCIPLES
 - ACTIVE CONTROL
- ° GENERAL LICENSE
 - NO SPECIAL TRAINING
 - PASSIVE CONTROL
- ° EXEMPT PRACTICES
 - NO CONTROL AFTER DISTRIBUTION

GENERAL LICENSE PROGRAM

- ° 10 CFR 31.5 CREATES GENERAL LICENSES FOR CERTAIN MEASURING, GAUGING, ILLUMINATING, AND CONTROL DEVICES
- ° 10 CFR 32.51 PROVIDES FOR MANUFACTURERS TO DISTRIBUTE GENERALLY LICENSED DEVICES VIA A SPECIFIC LICENSE
- ° MANUFACTURERS REPORT QUARTERLY TO NRC OR TO AGREEMENT STATE ALL TRANSFERS

GENERAL LICENSE PROGRAM (CONT.)

- ° ABOUT 54 MANUFACTURERS LICENSED BY NRC
- ° ABOUT 76 MANUFACTURERS LICENSED BY AGREEMENT STATE
- ° ABOUT 30,000 NRC GENERAL LICENSEES
- ° ABOUT 400,000 DEVICES

GENERAL LICENSE PROGRAM (CONT.)

- GENERAL LICENSEE REQUIRED TO REPORT THEFT OR LOSS AND NOTIFY NRC OF INCIDENTS
- GENERAL LICENSEE MAY ONLY TRANSFER TO SPECIFIC LICENSEE

PROBLEMS

- ° LOSS OF CONTROL
- ° QUALITY OF DEVICE
- ° GREATER THAN CLASS C WASTE
- ° LOW REGULATORY PRIORITY

QUESTIONS BEING ADDRESSED

- IS GENERAL LICENSE APPROACH VIABLE?
- ARE RESPONSIBILITIES CLEAR AND COMPLIED WITH?
- ARE DEVICES ACCEPTABLE?

INPUT TO REVIEW OF PROGRAM

- ° EXTENSIVE INTERACTIONS WITH AND
REVIEWS BY REGIONAL AND AGREEMENT
STATE PERSONNEL
- ° RECEIVED 24 RESPONSES TO DRAFT PAPER
- ° STRONG SUPPORT FOR DOING MORE
- ° OCCASIONAL COMMENT ON ABOLISHING THE
GENERAL LICENSE

PLANS FOR IMPROVING AND UPDATING
PROGRAM

- ° IMPROVE CONTROL
 - ANNUAL REPORTING FROM RESPONSIBLE INDIVIDUAL
 - COMPUTERIZE QUARTERLY TRANSFER REPORTS
 - MANUFACTURER INFORM GENERAL LICENSEE OF DISPOSAL COSTS
 - REDEFINE DEVICES THAT QUALIFY FOR GENERAL LICENSE

PLANS FOR IMPROVING AND UPDATING
PROGRAM (CONT.)

- ° ENHANCE QUALITY OF DEVICES
 - THIRD PARTY TESTING OF DEVICES
 - PERFORMANCE-ORIENTED QUALITY ASSURANCE RULE

- ° GREATER THAN CLASS C WASTE
 - SAME PROBLEM AS WITH SPECIFIC LICENSEE
 - ADDRESS WHEN RESPOND TO SRM ON GTCC (LATE 1989)

- ° QUALITY OF LICENSING REVIEW

USE OF STAFF RESOURCES

- ° FY90 (2 FTE), FY91 (4 FTE)
 - MAINTAIN TRACKING
 - DEVELOP REPORTING REQUIREMENT
 - INCREASE FOLLOWUP INSPECTION
- ° FY91 (2 FTE)
 - THIRD PARTY TESTING
 - VENDOR QUALITY ASSURANCE
- ° OTHER INITIATIVES WILL BE PROPOSED
IN FUTURE BUDGETS

CONCLUSIONS

- ° CONTINUE WITH GENERAL LICENSE PROGRAM WITH INCREASED ATTENTION GIVEN TO IT
- ° IMPROVE CONTROLS OVER GENERALLY LICENSED DEVICES
- ° ENCHANCE QUALITY OF GENERALLY LICENSED DEVICES

ANTICIPATED RESOURCE REQUIREMENTS FOR GENERAL LICENSE STUDY INITIATIVES

<u>Activity</u>	<u>FTE Required</u>			<u>FTE Already Allocated</u>		
	<u>FY90</u>	<u>FY91</u>	<u>FY92-94</u>	<u>FY90</u>	<u>FY91</u>	<u>FY92-94</u>
Maintain tracking of generally-licensed devices, develop rule for expanded annual survey and increase inspection effort	2.0	4.0	4.0	2.0	4.0	4.0
Review third-party testing program-tester qualifications-test results	0.0	1.0	2.0	0.0	1.0	1.0
Review vendor QA programs/increase licensing and inspection effort	0.0	1.0	4.0	0.0	1.0	1.0
Expand oversight of Agreement State program and provide more technical assistance to States	3.1	3.1	3.1	1.1*	1.1*	1.1*
Require certain devices to be specifically-licensed	0.0	0.0	5-10	0.0	0.0	0.0

* This also includes resources available to provide technical assistance to States regarding specific license activities

There is an aggregate requirement for 1.5 FTE in FY90-FY91 within the Office of Research (RES) to participate in the recommended rulemaking activities.