

July 26, 2006

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Dennis R. Lawyer  
Health Physicist, Commercial and R&D Branch  
Division of Nuclear Materials Safety, Region 1  
Nuclear Regulatory Commission  
475 Allendale Road  
King of Prussia, PA 19406-1415

Dear Mr. Lawyer,

**Re: License # 29-28330-01**

03030943

We would like to re-submit our application to amend our radioactive license # 29-28330-01 to include **Dr. Warren Maresca** as one of our authorized users for 10 CFR 35.100 and 200 materials. We are enclosing the following documents to support this application:

1. Certificates of his didactic training from the Institute for Nuclear medical education
2. A preceptor attestation of his practical experience with radiation signed by myself as an authorized user
3. A preceptor attestation and a letter of his practical experience with radiation specific to eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, etc. signed by an authorized nuclear pharmacist.

We hope that these documents will satisfy your requirements for approving Dr. Warren Maresca as an authorized user. If you have further question, please call our consulting physicist, Jessie Z. Trivino, M.S. at (201) 906-1803. Thank you very much for your immediate attention.

Sincerely,

John Capitanelli, M.D.  
Medical Director and RSO

Encls.

A Division of Cardiology Associates

(Ref 138561)

999 McBride Avenue, West Paterson, New Jersey 07424 973-256-8106

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NMSS/RGNI MATERIALS-002

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion and Competency

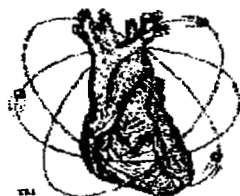
*This document is to attest that*

Warren L. Maresca, MD, FACC

*has successfully completed the didactic program*

## RADIOPHARMACEUTICALS AND CHEMISTRY

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.  
This program provides the following levels of accomplishment:*



- 50 Didactic Instructional Hours (DIH)  
(In compliance with 18CFR25 and Agreement States)
- 5 Continuing Education Units (CEU)
- 50 Technical/Professional Credit specified by the  
American Pharmaceutical Association and the  
American Association of Health Physicists\*

\*American Association of Health Physicists (AAHP) is a non-profit organization dedicated to the advancement of health physics education and research.

29 June 1996  
Date Class Commenced

Charles H. Rose

Authorized Signature

191621

Affidavit of Competency

### Institute for Nuclear Medical Education

5690 Airport Blvd., Suite 101, Boulder, Colorado 80301 — 800-548-4024

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

# NUCLEAR MEDICAL EDUCATION PROGRAM

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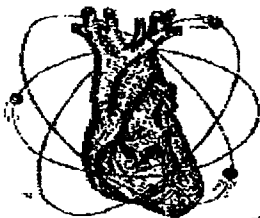
**WARREN L. MARESCA, M.D., F.A.C.C.**

*has successfully completed the didactic program*

## PRINCIPLES OF RADIATION PHYSICS

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 50** Didactic Instructional Hours (DIH)  
(in compliance with 10CFR35)
- 5** Continuing Education Units (CEU)
- 50** Continuing Medical Education (CME)
- 50** Technical/Professional Credit specified by the  
American Pharmaceutical Association and the  
American Association of Health Physicists\*

\*All hours of attendance will be provided to regulatory agencies upon request.

**2 March 1996**

**Date Class Commenced**

  
Authorized Signature

Affidavit of Competency

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5171 Eldorado Springs Drive, Boulder, CO 80303 — 800-548-9024

1111 FIVE 03/04

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

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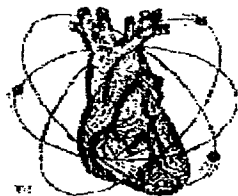
Warren L. Maresca, MD, FACC

*has successfully completed the didactic program*

## MEDICAL RADIATION PROTECTION

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

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- 50 Technical/Professional Credit specified by the  
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American Association of Health Physicists\*

\*American Association of Health Physicists, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 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3813, 3814, 3815, 3816, 3817, 3818, 3819, 3820, 3821, 3822, 3823, 3824, 3825, 3826, 3827, 3828, 3829, 3830, 3831, 3832, 3833, 3834, 3835, 3836, 3837, 3838, 3839, 3840, 3841, 3842, 3843, 3844, 3845, 3846, 3847, 3848, 3849, 3850, 3851, 3852, 3853, 3854, 3855, 3856, 3857, 3858, 3859, 3860, 3861, 3862, 3863, 3864, 3865, 3866, 3867, 3868, 3869, 3870, 3871, 3872, 3873, 3874, 3875, 3876, 3877, 3878, 3879, 3880, 3881, 3882, 3883, 3884, 3885, 3886, 3887, 3888, 3889, 3890, 3891, 3892, 3893, 3894, 3895, 3896, 3897, 3898, 3899, 3900, 3901, 3902, 3903, 3904, 3905, 3906, 3907, 3908, 3909, 3910, 3911, 3912, 3913, 3914, 3915, 3916, 3917, 3918, 3919, 3920, 3921, 3922, 3923, 3924, 3925, 3926, 3927, 3928, 3929, 3930, 3931, 3932, 3933, 3934, 3935, 3936, 3937, 3938, 393

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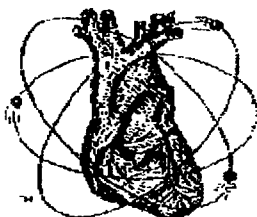
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American Pharmaceutical Association and the  
American Association of Health Physicists\*

\*American Association of Health Physicists, 1994, p. 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000

**13 April 1996**  
Date Class Commenced

Authorized Signature

**191384**  
Affidavit of Competency

## INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

5171 Eldorado Springs Drive, Boulder, CO 80303 — 800-548-4024

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education.

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**Mallinckrodt**

Mallinckrodt Inc.  
26 Chapin Road, Unit 1110  
P.O. Box 671  
Pine Brook, NJ 07058

Tele: 973 227-0179  
Fax: 973 227-0678  
[www.mallinckrodt.com](http://www.mallinckrodt.com)

June 25, 2006

North Jersey Nuclear Diagnostic  
999 McBride Ave  
West Paterson, NJ 07424

Subject: Authorized User Training

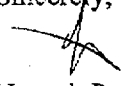
To Whom It May Concern:

This letter is to inform the interest party of items observed at Mallinckrodt nuclear pharmacy in Pine Brook, NJ on 06/21/2006 by Warren Maresca, M.D. Warren Maresca, M.D. has observed elution of Ultra-TechneKow DTE generator manufactured by Mallinckrodt Inc. Warren Maresca, M.D. observed following items during the radio pharmacy visit at Mallinckrodt nuclear pharmacy in Pine Brook, NJ:

- Molybdenum-99m Breakthrough test / Alumina Breakthrough test
- Preparation of radiopharmaceutical cold kit
- Dispensing of a radiopharmaceutical dose
- Packaging and monitoring of a simulated incoming and outgoing radioactive package
- Segregation of radioactive waste

Please contact Yogesh Patel at (800) 261-0811 with any questions or concerns.

Sincerely,

  
Yogesh Patel, PharmD  
Pharmacy Manager - Pine Brook, NJ Facility  
Tyco Healthcare / Mallinckrodt Inc.

NRC FORM 313A  
(04-2005)

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 10/31/2005**MEDICAL USE TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION****PART I -- TRAINING AND EXPERIENCE**

**Note:** Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35).

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

*DR. WARREN L. MARESCA, AUTHORIZED USER, 10CFR190, 10CFR290*

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

**3. CERTIFICATION**

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- c. Provide completed Part II Preceptor Attestation, items 11a through 11d.  
Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

**4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO),  
AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR  
AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS**

- a. Provide a copy of the license or broadscope permit listing the current authorization and (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

**5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical**

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	INSTITUTE FOR NUCLEAR MEDICAL EDUCATION	75	4/13/96
Radiation Protection	"	25	5/11/96
Mathematics Pertaining to the Use and Measurement of Radioactivity	"	25	3/2/96
Radiation Biology	"	25	5/11/96
Chemistry of Byproduct Material for Medical Use	"	50	6/29/96
OTHER			

## APPENDIX B

NRC FORM 313A  
(04-2005)

U.S. NUCLEAR REGULATORY COMMISSION

## MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
ORDERING RECEIVING & UNPACKAGING RADIOACTIVE MATERIALS.	JOHN CAPITALELLI, MD.	NORTH JERSEY NUCLEAR DIAGNOSTIC CENTER	200 HOURS
RADIATION SURVEYS	"	#29-28330-C1	
PERFORMING QC PROCEDURES ON DOSE CALIBRATOR	"	"	
PROPER OPERATION OF SURVEY METERS.	"	"	
CALCULATING MEASURING & SAFELY PREPARING PATIENT DOSES	"	"	

## 6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Tc-99m	NUCLEAR CARDIAC	300	JOHN CAPITALELLI, MD.	NORTH JERSEY NUCLEAR	600 HOURS
Tl-201	STRESS TESTING	TOTAL	"	DIAGNOSTIC CENTER #29-28330-C1	

PAGE 2



NRC FORM 313A  
(04-2005)

U.S. NUCLEAR REGULATORY COMMISSION

**MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)****6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)**

Training Element	Type of Training *	Location and Dates
N/A		

\* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

**7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists**

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
N/A			

**8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE**

- ☐ YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
- ☐ N/A of N/A the RSO for License No. \_\_\_\_\_

**9. MEDICAL PHYSICIST -- ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE**

- ☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics
- ☐ N/A (35.961) or medical physics (35.51) under the supervision of \_\_\_\_\_
- N/A and
- ☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and
- ☐ N/A for topics identified in item 6a) for (specify use or device) \_\_\_\_\_ under the supervision of \_\_\_\_\_ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) \_\_\_\_\_

## APPENDIX B

NRC FORM 313A  
(04-2005)

U.S. NUCLEAR REGULATORY COMMISSION

## MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):

A. Name of Supervisor

JOHN CARIMONE, M.D.

B. Supervisor is:

☒ Authorized User☐ Authorized Medical Physicist☒ Radiation Safety Officer☐ Authorized Nuclear PharmacistC. Supervisor meets requirements of Part 35, Section(s) 190, 290, 990  
for medical uses in Part 35, Section(s) 100, 200, 500

D. Address

E. Materials License Number

## PART II -- PRECEPTOR ATTESTATION

**Note:** This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 35.690 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

☐ has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) \_\_\_\_\_, as documented in section(s) GA & 68 of this form.

11b. Select one

N/A

☐ meets the requirements in ☐ 35.50(e), ☐ 35.51(c), ☐ 35.390(b)(1)(ii)(G), ☐ 35.690(c) for \_\_\_\_\_ types of use, as documented in section(s) \_\_\_\_\_ of this form.

☐ N/A

11c.

☐ has achieved a level of competency sufficient to operate a nuclear pharmacy (for 35.980); **OR**

☐ has achieved a level of competency sufficient to function independently as an authorized \_\_\_\_\_ for \_\_\_\_\_ uses (or units); **OR**

☐ has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; **OR**

☐ N/A

11d.

☐ I am an Authorized Nuclear Pharmacist; **OR** ☐ I am a Radiation Safety Officer; **OR**

☐ I meet the requirements of \_\_\_\_\_ section(s) of 10 CFR Part 35 or equivalent Agreement State requirements to be a preceptor ☐ AU or ☐ AMP for the following byproduct material uses (or units): \_\_\_\_\_

A. Address 999 McBRIDE AVE.  
WEST PATERSON, N.J. 07424

B. Materials License Number

# 29-28330-01

C. NAME OF PRECEPTOR (print clearly)

JOHN CARIMONE, M.D.

D. SIGNATURE -- PRECEPTOR

E. DATE

3/8/06

PAGE 4

## APPENDIX B

NRC FORM 315A (04-2005)		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005	
<b>MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION</b>					
<b>PART I - TRAINING AND EXPERIENCE</b>					
<b>Note:</b> Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35).					
1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)					
<u>DR. WARREN L. MALESKA, AUTHORIZED USER, 10 CFR 35.50, 10 CFR 290</u>					
2. For Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed					
<b>3. CERTIFICATION</b>					
a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)					
b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).					
c. Provide completed Part II Preceptor Attestation, Items 11a through 11d. Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.					
<b>4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS</b>					
a. Provide a copy of the license or broadscope permit listing the current authorization and (b) or (c)					
b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).					
c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).					
<b>5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical</b>					
<b>Description of Training</b>		<b>Location</b>		<b>Clock Hours</b>	
Radiation Physics and Instrumentation		N/A			
Radiation Protection					
Mathematics Pertaining to the Use and Measurement of Radioactivity					
Radiation Biology					
Chemistry of Byproduct Material for Medical Use					
OTHER					



APPENDIX B

NRC FORM 313A (04-2005)		U.S. NUCLEAR REGULATORY COMMISSION	
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)			
Training Element	Type of Training*	Location and Dates	
N/A			

\* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists			
Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
N/A			

8. RADIATION SAFETY OFFICER (RSO) - ONE-YEAR FULL-TIME EXPERIENCE

☐ YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.

☐ N/A of N/A the RSO for License No. \_\_\_\_\_

9. MEDICAL PHYSICIST - ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE

☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics

☐ N/A (35.961) or medical physics (35.51) under the supervision of N/A and \_\_\_\_\_

☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and

☐ N/A for topics identified in item 6a) for (specify use or device) \_\_\_\_\_ under the supervision of \_\_\_\_\_ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) \_\_\_\_\_

PAGE 3

## APPENDIX B

NRC FORM 313A (04-2005)		U.S. NUCLEAR REGULATORY COMMISSION	
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
5c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)			
Training Element	Type of Training *	Location and Dates	
N/A			

\* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists			
Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
N/A			

8. RADIATION SAFETY OFFICER (RSO) - ONE-YEAR FULL-TIME EXPERIENCE

☐ YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.

☐ N/A of N/A the RSO for License No. \_\_\_\_\_.

9. MEDICAL PHYSICIST - ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE

☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics

☐ N/A (35.961) or medical physics (35.51) under the supervision of \_\_\_\_\_

N/A and

☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and

☐ N/A for topics identified in item 6a) for (specify use or device) \_\_\_\_\_ under the supervision of \_\_\_\_\_ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) \_\_\_\_\_.

PAGE 3

This is to acknowledge the receipt of your letter/application dated

7/26/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 29-28330-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 139224.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.