

30-06986

FORM NRC-313 I (3-80) 10 CFR 30		U.S. NUCLEAR REGULATORY COMMISSION		1. APPLICATION FOR: (Check and/or complete as appropriate)	
APPLICATION FOR BYPRODUCT MATERIAL LICENSE INDUSTRIAL				a. NEW LICENSE	
				b. AMENDMENT TO: LICENSE NUMBER	
				c. RENEWAL OF: LICENSE NUMBER 20-14809-1	
<i>See attached instructions for details.</i> Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.					
2. APPLICANT'S NAME (Institution, firm, person, etc.) Donald G. Comb, PhD TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION 617-927-5054			3. NAME AND TITLE OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION Donald G. Comb, President TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION 617-927-5054		
4. APPLICANT'S MAILING ADDRESS (Include Zip Code) (Address to which NRC correspondence, notices, bulletins, etc., should be sent.) New England Biolabs Inc. 32 Tozer Road Beverly, MA 01915			5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED (Include Zip Code) NEB-283 Cabot St. Beverly, MA 01915 NEB-32 Tozer Road, Beverly, MA 01915		
(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)					
6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL (See Items 16 and 17 for required training and experience of each individual named below)					
		FULL NAME		TITLE	
a.	Donald G. Comb	Applicant, 6640		President, New England Biolabs, Inc.	
b.	Roger L. Knott	Assistant, 9/10		Vice President, Organic Synthesis Div., New England Biolabs, Inc.	
c.		Date Check Rec'd 8/15/81 Received by Brown			
7. RADIATION PROTECTION OFFICER Donald G. Comb			Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.		
8. LICENSED MATERIAL					
LINE NO.	ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	NAME OF MANUFACTURER AND MODEL NUMBER (If Sealed Source)	MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME	
	A	B	RECEIVED BY LFMB 9/10/81 Sept. 5 Reg Brown	D	
(1)	Carbon 14	Liquid	Date	10 millicuries	
(2)	Hydrogen 3	Liquid	Log.	50. millicuries	
(3)	Phosphorus 32	Liquid	By	10 millicuries	
(4)	Sulfur 35	Liquid	Orig. To	5 millicuries	
DESCRIBE USE OF LICENSED MATERIAL E					
(1)	Enzyme assays and biological synthesis of nucleic acids and proteins				
(2)	8507260163 850703 REG1 LIC30				
(3)	20-14809-01 PDR				
(4)	COPIES SENT TO OFF. OF INSPECTION AND ENFORCEMENT				

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9. STORAGE OF SEALED SOURCES

LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)			
(2)			
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS

LINE NO.	TYPE OF INSTRUMENT A	MANUFACTURER'S NAME B	MODEL NUMBER C	NUMBER AVAILABLE D	RADIATION DETECTED (alpha, beta, gamma, neutron) E	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F
(1)	Survey meter	Picker	A600180C	2	alpha, beta, gamma	0.1 mr/hr
(2)	Scintillation Counter	Packard	Tri-Carb	1	beta-gamma	20 counts/min
(3)						
(4)						

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

<input type="checkbox"/> a. CALIBRATED BY SERVICE COMPANY NAME, ADDRESS, AND FREQUENCY	<input type="checkbox"/> b. CALIBRATED BY APPLICANT <i>Attach a separate sheet describing method, frequency and standards used for calibrating instruments. Survey meter-internal standard Scintillation: Standards supplied by manufacturer</i>
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12. PERSONNEL MONITORING DEVICES

TYPE (Check and/or complete as appropriate.) A	SUPPLIER (Service Company) B	EXCHANGE FREQUENCY C
<input checked="" type="checkbox"/> (1) FILM BADGE <input type="checkbox"/> (2) THERMOLUMINESCENCE DOSIMETER (TLD) <input type="checkbox"/> (3) OTHER (Specify): _____ 	ICN	<input type="checkbox"/> MONTHLY <input checked="" type="checkbox"/> QUARTERLY <input type="checkbox"/> OTHER (Specify): _____

13. FACILITIES AND EQUIPMENT (Check where appropriate and attach annotated sketch(es) and description(s).

- ☐ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.
☐ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.
☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED
ICN

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE. The very low level use of primarily tritium in this laboratory allows about 100 μ curies to be disposed of down the drain per month. Liquid ^{32}P is stored in a hood for natural decay and when no longer detected with survey meter-dispose down drain.

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. **RADIATION PROTECTION PROGRAM.** Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures (if needed), day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.
16. **FORMAL TRAINING IN RADIATION SAFETY.** Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.
 - a. Principles and practices of radiation protection.
 - b. Radioactivity measurement standardization and monitoring techniques and instruments.
 - c. Mathematics and calculations basic to the use and measurement of radioactivity.
 - d. Biological effects of radiation.
17. **EXPERIENCE.** Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

WARNING.—18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

a. LICENSE FEE REQUIRED (See Section 170.31, 10 CFR 170) <div style="font-size: 1.5em; margin-left: 100px;">\$150.00</div>	b. CERTIFYING OFFICIAL (Signature) <div style="font-family: cursive; font-size: 1.2em;">Donald G. Comb</div>
(1) LICENSE FEE CATEGORY:	c. NAME (Type or print) Donald G. Comb
(2) LICENSE FEE ENCLOSED: \$ 150.00	d. TITLE President e. DATE 8/27/81



32 Tozer Road Beverly, MA, U.S.A. 01915

(617) 927-5054

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

15. Radiation protection program:

The routine use of isotopes in these laboratories is for enzyme assay and DNA sequencing. This involves a few μC of tritium and less than 100 μC of ^{32}P , ^{35}S and ^{14}C . We routinely check for spills by weekly or biweekly survey of work areas with paper disc swipes for scintillation counting. During the very infrequent use of larger amounts of isotopes careful confinement of glassware, pipettes, etc. is done ^{with} and surveys on the spot to detect any spills.

In all cases, a list of the amount and type of isotopes disposed of, either as liquid or solid is maintained.

16. Formal Training: Donald G. Comb

I have handled radioisotopes for 30 years. Used 100 mc of ^{14}C to synthesize sugars from 1954 to 1960 at the University of Michigan. Supplied NEN with some of the first ^{14}C -glucose sold commercially. At Harvard Medical School I prepared labelled nucleic acids from bacteria using 50 mc of ^{14}C or ^{32}P substrates. Formal courses in radiation safety were taken at the University of Michigan. I provided the safety training for many graduate students at Harvard Medical School.

17. See attached resumes for Donald G. Comb and Roger Knott

CURRICULUM VITAE

DONALD GEORGE COMB

Born:	July 10, 1927: Detroit, Michigan
1951	A.B., Wayne University, Michigan
1952	A.M., University of Michigan
1956	Ph.D., University of Michigan
1956-1958	Postdoctoral Fellow, American Cancer Society, Rackham Arthritis Research Unit, University of Michigan
1958-1960	Research Associate, Rackham Arthritis Research Unit, University of Michigan
1958-1960	Instructor in Biological Chemistry, Medical School, University of Michigan
1960-1964	Assistant Biochemist, Massachusetts General Hospital, Boston, Massachusetts
1961-1962	Research Associate in Biological Chemistry, Harvard Medical School, Boston, Massachusetts
1962-1964	Associate in Biological Chemistry, Harvard Medical School, Boston, Massachusetts
1964-1970	Assistant Professor of Biological Chemistry, Harvard Medical School, Boston, Massachusetts
1970-1971	Associate Professor of Biological Chemistry, Harvard Medical School, Boston, Massachusetts
1972-Present	President, New England Biolabs, Inc. Beverly, Massachusetts

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Radiation Safety Resume

Experience

Over the past 15 years I have worked with ^{32}P , ^{125}I , ^3H , ^{90}Sr . During my employment at Collaborative Research (1966-1980) I attended required radiation safety meetings and met with company radiation safety consultants on a regular basis.

Education A.B., M.S., Chemistry

College courses pertinent to radiation principles, measurements, standardization, monitoring, calculation, and biological effects are as follows:

Undergraduate- Boston University

Quantitative Analysis (used ^{90}Sr in lab)
Advanced Quantitative Analysis
Physical Chemistry
Physical Chemical Measurements
Physics II
Calculus III
Biochemistry (used ^{32}P in lab)

Graduate- Northeastern University

Analytical Separations
Advanced Inorganic III
Biochemistry III
Atomic & Molecular Structure
Kinetics

Roger L. Knott
189 McKay Street
Beverly, Massachusetts, 01915
Tel. (617) 922-7961

EDUCATION

A.B. Chemistry, (1969), Boston University, College of
Liberal Arts, Boston, Massachusetts.
M.S. Chemistry, (1974), Northeastern University, Graduate
School of Arts and Sciences, Boston,
Massachusetts.

EMPLOYMENT

Collaborative Research, Inc.
1365 Main Street
Waltham, Massachusetts.
(1966- present)

EXPERIENCE

SYNTHESIS (1979-1966)

Research and development of the modified phosphotriester method of oligodeoxynucleotide synthesis. Successful application of this technique to the rapid production of numerous oligomers of defined sequence, chain length 10-20, including molecular recombination linkers and custom syntheses.

Research and development of new protecting groups, phosphorylating agents, condensing agents, and deprotection procedures for oligonucleotide synthesis.

Synthesis of nuclease resistant (blocked) oligonucleotides.

SYNTHESIS - continued

Synthesis and purification of tetrahydrocannabinol derivatives for use in RIA.

Enzymatic preparation and isolation of homooligoribonucleotides of defined chain length. Chemical synthesis of ribo dimers. Isolation of ribo dimers and codons from digests.

Phosphorylation of ribonucleosides with unnatural bases.

Preparation of triphosphates in the dideoxy series and numerous oligonucleotides by the classical Khorana techniques.

Chemical modification of thymidylate oligomers for use as inhibitors of RNA dependent-DNA polymerase.

Investigation of chemical ligation techniques for joining deoxyribooligonucleotides.

Synthesis of potential antifertility compounds, based on ergoline (LSD), benzoquinoline, and benz indole derivatives.

Synthesis of phosphorylated nitrogen mustards.

Preparation of kilogram quantities of the pteridine, Homofolic Acid, and research and development of tetrahydrohomofolate derivatives, resulting in three U.S. Patents for synthesis, production, and utilization of 5-Methyltetrahydrohomofolate in cancer chemotherapy.

ANALYTICAL

NMR, IR, UV, MS, GC

Chromatographic separations using ion exchange, partition, gel filtration, electrophoresis, and reverse phase techniques.

Development of affinity chromatographic materials.

Development of reverse phase HPLC systems for purification and analysis of oligonucleotides.

Enzymatic analysis of nucleotides, including DNA sequencing by mobility shift analysis after two-dimensional homochromatography of ^{32}P labeled digests.

SUPERVISORY (1977-1979)

TECHNICAL PRODUCTION MANAGER

Responsible for production, inventory, and quality control of hundreds of defined sequence nucleotides. Trained and supervised eight chemists, improved existing production techniques, planned custom syntheses, and provided customer services.

SENIOR RESEARCH CHEMIST

Supervision of two research chemists for in-house research and development.

ADDITIONAL PERSONAL INFORMATION

Prior to 1966, I was employed by Beverly and Salem Hospital Laboratories as a clinical laboratory technician (1961-1966).

Married, three children. Born Salem, MA, August 13, 1940.

Member of the American Chemical Society.

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PUBLICATIONS

1. The Synthesis of N⁵-Methyltetrahydrohomofolic Acid and Related Reduced Derivatives of Homofolic Acids, R. Knott and A. Taunton-Rigby, presented at the ACS National Meeting, Washington, D.C. (1971).
2. Comparative Antitumor Activity of 5-Methyltetrahydrohomofolate (CH₃-H₄HF) and Tetrahydrohomofolate (H₄HF) in Mice. L.C. Mishra, A.S. Parmar, J.A.R. Mead, R. Knott, A. Taunton-Rigby, and O.M. Friedman, Proceeding of the American Association for Cancer Research, 13, 76 (1972).
3. Inhibition of Leukemia Utilizing 5-Methyltetrahydrohomofolate, J.A.R. Mead, R.L. Knott, and A. Taunton-Rigby, U.S. Patent, 3, 856, 959 (1974).
4. Synthesis of N⁵-Methyltetrahydrohomofolic Acid and Related Reduced Derivatives of Homofolic Acid, R.L. Knott, and A. Taunton-Rigby, U.S. Patent, 3, 870, 719 (1975).
5. Production of N⁵-Methyltetrahydrohomofolic Acid and Related Reduced Derivatives of Homofolic Acid, R. L. Knott, A. Taunton-Rigby, and J.A.R. Mead, U.S. Patent, 3, 983, 118 (1976).
6. Synthesis of a Tridecanuceptide Complementary to a Terminally Redundant Sequence of Rous Sarcoma Virus 355 DNA, John P. Hachmann and Roger L. Knott, to be submitted for publication (BBRC).

UNIT	NO. 1	NO. 2	NO. 3	NO. 4	NO. 5	NO. 6	NO. 7	NO. 8	NO. 9	NO. 10	NO. 11	NO. 12	NO. 13	NO. 14	NO. 15	NO. 16	NO. 17	NO. 18	NO. 19	NO. 20	NO. 21	NO. 22	NO. 23	NO. 24	NO. 25	NO. 26	NO. 27	NO. 28	NO. 29	NO. 30	NO. 31	NO. 32	NO. 33	NO. 34	NO. 35	NO. 36	NO. 37	NO. 38	NO. 39	NO. 40	NO. 41	NO. 42	NO. 43	NO. 44	NO. 45	NO. 46	NO. 47	NO. 48	NO. 49	NO. 50	NO. 51	NO. 52	NO. 53	NO. 54	NO. 55	NO. 56	NO. 57	NO. 58	NO. 59	NO. 60	NO. 61	NO. 62	NO. 63	NO. 64	NO. 65	NO. 66	NO. 67	NO. 68	NO. 69	NO. 70	NO. 71	NO. 72	NO. 73	NO. 74	NO. 75	NO. 76	NO. 77	NO. 78	NO. 79	NO. 80	NO. 81	NO. 82	NO. 83	NO. 84	NO. 85	NO. 86	NO. 87	NO. 88	NO. 89	NO. 90	NO. 91	NO. 92	NO. 93	NO. 94	NO. 95	NO. 96	NO. 97	NO. 98	NO. 99	NO. 100	NO. 101	NO. 102	NO. 103	NO. 104	NO. 105	NO. 106	NO. 107	NO. 108	NO. 109	NO. 110	NO. 111	NO. 112	NO. 113	NO. 114	NO. 115	NO. 116	NO. 117	NO. 118	NO. 119	NO. 120	NO. 121	NO. 122	NO. 123	NO. 124	NO. 125	NO. 126	NO. 127	NO. 128	NO. 129	NO. 130	NO. 131	NO. 132	NO. 133	NO. 134	NO. 135	NO. 136	NO. 137	NO. 138	NO. 139	NO. 140	NO. 141	NO. 142	NO. 143	NO. 144	NO. 145	NO. 146	NO. 147	NO. 148	NO. 149	NO. 150	NO. 151	NO. 152	NO. 153	NO. 154	NO. 155	NO. 156	NO. 157	NO. 158	NO. 159	NO. 160	NO. 161	NO. 162	NO. 163	NO. 164	NO. 165	NO. 166	NO. 167	NO. 168	NO. 169	NO. 170	NO. 171	NO. 172	NO. 173	NO. 174	NO. 175	NO. 176	NO. 177	NO. 178	NO. 179	NO. 180	NO. 181	NO. 182	NO. 183	NO. 184	NO. 185	NO. 186	NO. 187	NO. 188	NO. 189	NO. 190	NO. 191	NO. 192	NO. 193	NO. 194	NO. 195	NO. 196	NO. 197	NO. 198	NO. 199	NO. 200	NO. 201	NO. 202	NO. 203	NO. 204	NO. 205	NO. 206	NO. 207	NO. 208	NO. 209	NO. 210	NO. 211	NO. 212	NO. 213	NO. 214	NO. 215	NO. 216	NO. 217	NO. 218	NO. 219	NO. 220	NO. 221	NO. 222	NO. 223	NO. 224	NO. 225	NO. 226	NO. 227	NO. 228	NO. 229	NO. 230	NO. 231	NO. 232	NO. 233	NO. 234	NO. 235	NO. 236	NO. 237	NO. 238	NO. 239	NO. 240	NO. 241	NO. 242	NO. 243	NO. 244	NO. 245	NO. 246	NO. 247	NO. 248	NO. 249	NO. 250	NO. 251	NO. 252	NO. 253	NO. 254	NO. 255	NO. 256	NO. 257	NO. 258	NO. 259	NO. 260	NO. 261	NO. 262	NO. 263	NO. 264	NO. 265	NO. 266	NO. 267	NO. 268	NO. 269	NO. 270	NO. 271	NO. 272	NO. 273	NO. 274	NO. 275	NO. 276	NO. 277	NO. 278	NO. 279	NO. 280	NO. 281	NO. 282	NO. 283	NO. 284	NO. 285	NO. 286	NO. 287	NO. 288	NO. 289	NO. 290	NO. 291	NO. 292	NO. 293	NO. 294	NO. 295	NO. 296	NO. 297	NO. 298	NO. 299	NO. 300	NO. 301	NO. 302	NO. 303	NO. 304	NO. 305	NO. 306	NO. 307	NO. 308	NO. 309	NO. 310	NO. 311	NO. 312	NO. 313	NO. 314	NO. 315	NO. 316	NO. 317	NO. 318	NO. 319	NO. 320	NO. 321	NO. 322	NO. 323	NO. 324	NO. 325	NO. 326	NO. 327	NO. 328	NO. 329	NO. 330	NO. 331	NO. 332	NO. 333	NO. 334	NO. 335	NO. 336	NO. 337	NO. 338	NO. 339	NO. 340	NO. 341	NO. 342	NO. 343	NO. 344	NO. 345	NO. 346	NO. 347	NO. 348	NO. 349
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Call 1-800-368-2262

U.S. TV Network

QUANTITY	UNIT	GRADE	QTY REQ	QTY HSD	CUR
6026305509	KNOTT	ROS FL70			
12.803	ADV IN CWR1	2.0 A			
12.803	ADV ON CWR1	2.0 B			
6026305509	KNOTT	ROS WNT1			
12.802	ADV IN CWR2	2.0 B			
12.803	ADV ON CWR2	2.0 B			
6026305509	KNOTT	ROS SPT1			
12.803	CRG CWR PRO	2.0 C			
6026305509	KNOTT	ROS SMT1			
12.803	ADV IN CWR3	2.0 B			
6026305509	KNOTT	ROS FAT1			
12.804	STERECHEMENT	2.0 C			
6026305509	KNOTT	ROS WNT2			
12.803	STERECHEMENT	2.0 B			
12.876	FLICK CRG RE	2.0 B			
6026305509	KNOTT	ROS SPT2			
12.804	CRG CARPOS	2.0 A			
12.877	MECH OR REZ	2.0 B			
6026305509	KNOTT	ROS FL72			
12.821	ABALVT SEP	2.0 B			
90.821	BLOCHEM 1	2.0 B			
6026305509	KNOTT	ROS WNT3			
12.822	ELECTANL CH	2.0 B			
12.805	SYCHNG SYN 1	2.0 B			
90.872	BLOCHEM 2	2.0 B			
6026305509	KNOTT	ROS SPT3			
12.873	KNOTT 100	2.0 A			

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GEORGE MASTER OF SCIENCE
16 JUNE 76

16 JUN 74

DATE

Linda Allen

APR 23 1979

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