Non - Proprietary Information

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July 9, 1987

U.S. Nuclear Regulatory Commission
Director of the Office of Nuclear
Reactor Regulations
Washington, D.C. 20555

Dear Sir:

REF. (a) Cintichem Letter, WGR 9/18/86
(b) NRC Letters, 50-54, 12/30/86
and 2/11/87

Title 10 of the Code of Federal Regulations Part 50.64 allows reactor licensees to apply for a unique purpose exemption from the requirement to convert from high enriched uranium (HEU) to low enriched uranium (LEU) for reactor fuel. Generic letter 86-12 provides specific guidance by which licensees may apply for such exemptions and also the criteria by which they may be granted by the Commission. Accordingly, Cintichem applied for such a unique purpose exemption by letter referenced above (Ref.a) and NRC requested additional information by letters referred to in (b) above. In the interest of coherence Cintichem hereby restates its original arguments of reference (a) with elaboration in response to NRC's request for additional information in in reference (b).

I. INTRODUCTION

This application reviews the isotope production program at the Tuxedo, N.Y. reactor facility which is the sole domestic source of vital radioisotopes for certain medical applications. The reliable and continuous supply of these isotopes cannot be reasonably accomplished without the continued use of HEU fuel. This application also details the unique status of the Cintichem reactor as a commercial enterprise which functions within and is influenced by a worldwide market and which is dependent upon the economic viability of the program.

Cintichem's 5 MW MTR research reactor and adjoining hot laboratory are used primarily for the production of medical radioisotopes. Target material is irradiated in the reactor core to produce the desired isotopes. The radioactive targets are then transferred to the adjoining hot laboratory where the desired isotopes are chemically separated and packaged for shipment to hospitals and pharmaceutical firms throughout the world.

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The Cintichem facility is the only commercial supplier of reactor-produced isotopes in the United States. It also produces a substantial share of the world's needs of these isotopes. One in every four patients in U.S. hospitals benefits from a nuclear diagnostic procedure and seventy percent of all nuclear diagnostic procedures are performed with reactor-produced isotopes, amounting to more than 125 million *in vivo* and *in vitro* diagnostic tests conducted yearly in the U.S.

Cintichem's production of medical radioisotopes is in he national interest because Cintichem is the only domestic source of several vital isotopes that are essential for the practice of nuclear medicine. Table A below shows the portion of the U.S. requirement for medical radioisotopes supplied by the Cintichem reactor and Table B shows the number of diagnostic tests that are accomplished with them.

TABLE A

Medical Isotopes	Approximate Amount From Cintichem
Mo99/Tc99m	54%
I-131	50%
Xe-133	13%
I-125	25%
P-32	100%

TABLE B

Procedure	No./Yr.	Percent Provided By Cintichem
IN VIVO TESTS:		
Mo99/Tc99m Diagnostic Scans[1]		
Brain	115,000	
Liver/Spleen	703,000	
Bone	2,021,000	
Thyroid	186,000	
Lung	752,000	
Heart	684,000	
Kidney	218,000	
TOTAL	4,679,000	54%
I-131 Diagnostic Scans[1]		
Thyroid	104,000	
Kidney	63,000	
TOTAL	167,000	50%
I-131 Therapy		
Thyroid	156,000	50%
Xe-133 Lung Scans	545,000	13%
Ir-192 Implants	1,068,000	50%
IN VITRO TESTS:		
I-125 Radioimmunoassay[2]	120,000,000	33%

1 Market Measures, Inc., 3rd Quarter 1986 - (Quarterly Reports of Products Used for In Vivo Radiodiagnostic Procedures Performed in U.S. Hospitals - By Organ).

2 Based on I-125 Customer's Share of In Vitro Market as reported in IMS America, 4th Quarter 1979, Hospital and Private Laboratories Survey, p.344.

II. TECHNICAL ISSUES

Medical radioisotopes, of necessity, are short lived. They cannot be stored or stocked for future use. Therefore, it is necessary that production facilities operate continuously (day to day) and reliably at a sustained capacity in order for the medical community to have these materials readily available at any time. Any interruption in the supply of these isotopes would have a significant negative impact on the practice of nuclear medicine.

The Cintichem facility maintains a preeminent role for supplying these vital medical radioisotopes within the United States. Statements from the Society of Nuclear Medicine and the American College of Nuclear Physicians attesting to this are being forwarded under separate cover.

Cintichem's role was achieved not only through the application of innovative technology but, more importantly, it is maintained by providing a continuous reliable supply of these short-lived isotopes. This facility must also stay viable economically as a commercial venture. Sustained reliability and economic viability then are essential for maintaining Cintichem's position as the preeminent supplier of these isotopes in the U.S. as well as a major supplier in the international market.

The NRC Regulatory Analysis of its originally proposed HEU rule expressed concerns about the societal cost from any loss of reactor capabilities. It stated that for facilities above 1-2 MW power, LEU conversion could have an impact on the source of neutrons necessary for production processes. Of most concern in the NRC's analysis was the capability to produce short-lived isotopes for medical research and diagnosis, which could be affected by temporary or permanent facility shutdowns, or by competitive market forces. The Regulatory Analysis stated that the provisions of the rule are intended to minimize any potential losses in facility capabilities and availability.

Cintichem fully appreciates and supports the NRC's concern for the societal cost of a reduction of the U.S.-produced radioisotope capacity. Cintichem also agrees with the NRC's stated desire that the rule's provisions, notably the "unique purpose" exemption provision, can be used to minimize the impact or prevent the loss of domestic reactor capabilities. The following are our reasons:

(a) <u>Conversion of the Cintichem reactor to low enriched fuel will have an adverse impact on the operating characteristics of the reactor for producing radioisotopes and other nuclear services. The result will be a 10% reduction in isotope production capacity and inevitable shortages of supply of medical isotopes to the U.S. market.</u> The known reduction of thermal flux, the change in neutron energy spectrum and the anticipated reduction in core excess reactivity will be detrimental to the isotope production program at Cintichem.

The IAEA LEU Core Conversion Guidebook (IAEA-TECDOC-233 App. F-1 MTR Benchmark Calculations) concludes that a hardened neutron energy spectrum and an approximate 10% reduction in the thermal neutron flux can be expected after

LEU conversion. This was confirmed in the Ford Reactor conversion to LEU. The Cintichem reactor is basically a thermal neutron source for producing radioisotopes and performing nuclear irradiation service. A 10% reduction in the thermal neutron flux will result in a 10% reduction in isotope production capacity. Simply put, radioisotope production is expressed as a function of # target atoms x cross section x flux x saturation factor. Target atoms, cross section and flux are scalers in this equation while the saturation factor is a time and halflife dependent variable which is asymptotic. Therefore, production capacity varies proportionately with flux and disproportionately with time, especially beyond one halflife of the radioisotope being produced.

The flux hardens with LEU conversion even while the power level of the core is maintained at 5 MW. Therefore, to produce the same number of thermal neutrons and correspondingly the same number of radioisotopes by thermal neutron induced nuclear reactions, the reactor power level would have to be increased by 10%. The Cintichem reactor cannot easily be run at 5.5 MW. This is due to the existing reactor cooling capabilities and present power level license limits. Similarly, radioisotope production could not be increased by increasing reactor operating time as the reactor now operates at an approximate 95% duty cycle. The 5% down time is necessary for reactor maintenance and refueling. Other constraints dictated by product specifications, such as product half lives and induced long lived contaminates also preclude the longer operating time as a solution to this problem.

This anticipated reduction in capacity cannot be overcome by adding more isotope production targets to the core because of the technical specification limits on the core coolant flow that can be diverted to cool targets. The specification is as follows:

> "The total primary coolant flow utilized by all in-core experiments shall meet the following requirements; fraction of core flow in experiments $\leq$ 1-5/6 (fraction of rated power production in fuel elements)."

The equation states that if all the rated power is produced in the fuel elements, then 1/6th of the core flow can be devoted to in-core experiments. If the experiments are fueled and produce a percentage of the total rated core power, then greater than 1/6th flow can be given to the experiments. Cintichem fission product isotope targets do produce fission power and therefore Cintichem allows the total experimental flow to be greater than 1/6th of the total core flow.

Knowing the flow rates through the isotope target stringers and the fuel elements, the percentage of the total core flow through all experiment positions is calculated. This actual experiment flow rate is then compared to the maximum allowed experiment flow rate. The maximum allowed experiment flow rate is calculated with the above technical specification formula using the known amount of power produced in the fueled experiments. This calculation is done at normal minimum total core flow rate of 2000 gpm. There is insufficient flow to add more fueled targets and therefore Cintichem is at the current limit for the number of Mo99 production targets. No more core space can be dedicated to fission product molybdenum production, given the limitations of the technical specifications, the present product mix and the current state of target technology. Increases in isotope capacities can only be achieved through tradeoffs. An increase in one isotope must be accommodated by reductions or changes in other products, services, or operating parameters.

Cintichem has reviewed the available data on control rod worth changes following a conversion from HEU to LEU fuel. Experimental and theoretical data indicate that a decrease in rod worths will be experienced. The whole core LEU demonstration at the Oak Ridge reactor and other sources have predicted that, in general, control rod worths would go down by approximately five percent with LEU fuel due to the harder neutron spectrum and less neutron absorption in the control rods relative to the fuel. A five percent reduction of control rod worths would decrease current operational maximum excess reactivity which is dictated by the technical specification limit on minimum shutdown margin. This reduction would decrease the operating time between refuelings and, because we run with the highest duty cycle practicable, extra shutdowns to refuel would decrease our productivity. This effect can be initially evaluated as follows:

	HEU Core	LEU Core
Gang Rod Worth	+9.35%	+8.88%
Xenon Equil.	-3.50%	-3.50%
Power Coeff.	-0.35%	-0.35%
Max.Worth Rod	-2.65%	-2.52%
Excess SDM	-0.50%	-0.50%
Allowable Excess Operating Delta K/K	+2.35%	+2.01%

Change in allowable excess Delta K/K = -14.5%

Therefore the allowable operating time between reactor fuel loadings will decrease by approximately 15% as a result of a 5% decrease in rod bank worth. This would result in a reduction in overall duty cycle and consequent reduction in isotope production capacity.

The reduction in thermal neutron flux and the anticipated loss in excess reactivity will reduce our current capacity to produce medical isotopes by >10%. There have been numerous occasions in the past (and there will undoubtedly be future occasions) when one of the foreign producers of medical isotopes will experience an interruption or a shortfall in production and Cintichem has had to go to maximum capacity to make up this shortage. If Cintichem loses the current capacity due to conversion to LEU, it will not be able to completely make up for future shortfalls. Since a large portion of the current domestic supply is dependent on the imports, there will be a shortage of medical isotopes in the U.S. as well as overseas. Additionally, any reduction of Cintichem's current capacity will limit our ability to maintain a preeminent role in the future expansion of the nuclear medical field. A brief history of Cintichem's experience in making up production lapses of foreign producers is presented in Table C.

(b) <u>It is uncertain that isotopes produced in an LEU core would be comparable in quality; product and waste requalifications would be necessary resulting in disturbance in the continuity of supply of important medical isotopes.</u> The reliable and continuous supply of medical isotopes (particularly Mo-99) could also be adversely affected due to changes in the characteristics of the product due to the anticipated changes in the neutron energy spectrum within the core. The isotopes and services that are currently provided from Cintichem's HEU fueled core could also be produced in an LEU fueled core but it is uncertain if they would be comparable in quality.

For example, the predominant isotope produced in the Cintichem facility is Mo-99. It is made through the fission reaction of U-235 and then it is separated from the other fission products by a process that has developed and evolved over more than 15 years. The production process is compatible with the plant design and physical capacity.

The Mo99 isotope is used as the active ingredient of a parenteral drug product and as such has been well qualified. It is characterized particularly to be free of transuranic elements. The anticipated change in the neutron flux energy spectrum within the core would increase the production of Pu-239 due to increased resonance capture in the U-238 which is present in the isotope production target. Cintichem believes that this would necessitate a requalification of this product.

Requalification would involve irradiating targets in a low enriched uranium core, processing the targets to remove the molybdenum, and then testing for conformance with specifications on radionuclidic purity, i.e. absence of gamma, beta, and alpha emitters. This testing generally requires the test material to be decayed and then analyzed on a mass spectrometer. (Mass spectrometers are generally not available for this type of radioactive material analysis.) Following this testing it would be necessary to make a

TABLE C

TABLE C - continued

finished drug product from this material, i.e. molybdenum-technitium generator, and then test the eluent from this product for radionuclidic purity, radiochemical purity, and pharmacological efficacy. This requalification would require the core to be in place and operating. The analysis would have to be done on the finished drug product and it would be a time-consuming process. Cintichem does not see how this can be accomplished without causing some disturbance in the continuity of supply of this isotope.

Requalification of our product is the paramount concern. However, it is almost as important to requalify the radioactive waste produced. 10 CFR 61 requires detailed classification and verification of waste isotopes and this classification is highly dependent on the waste plutonium content which changes significantly as the core's neutron energy spectrum changes. it therefore would be necessary to requalify the waste produced as thoroughly as the radioisotope products. This waste reclassification would be a time consuming complex process.

Making the overall requalification process even more complicated is the fact that actual conversion from HEU to LEU fuels is a long process. The anticipated method of core conversion would be to proceed from HEU to LEU by incrementally introducing LEU fuel elements into an HEU core. As the HEU elements become depleted, more LEU elements would be added, resulting, after a year or so, in a full LEU core. This process would result in the overall core neutron energy spectrum slowly changing from HEU to LEU. This could require continuous sampling, analysis, and requalification as the energy spectrum changes and would significantly add to the complexity and scope of the total requalification effort.

At present Cintichem does not see how this can be accomplished without, at worst, a significant interruption of the normal supply of medical isotopes or, at best, a significant added expense for continuous requalification during the conversion period. Cintichem believes that it is unreasonable to have to bear this added contingent economic burden as a consequence of converting to LEU.

(c) <u>Other services for non-medical customers will be threatened as a result of conversion to LEU.</u> Cintichem's major reason for operating its reactor is to produce radioisotopes for the medical community. We also have a program in which reactor service irradiations are performed for various non-medical use customers. The largest contingent in this category is to produce neutron transmutation-doped silicon. It is complementary to the radioisotope program and does not compete for reactor core space.

The doping of high purity silicon is done by the reaction, Si-30 (n, gamma) Si-31 --> P-31 + B. This reaction uses thermal neutrons to produce the desired phosphorous doping. Therefore, the higher the thermal flux the faster the crystal doping can be done. Reducing the thermal flux reduces doping productivity. On the other hand, fast neutron flux causes crystal defects to occur. With a harder flux spectrum, more fast neutron crystal damage will occur. Most silicon manufacturers are quite concerned with the fast to thermal flux ratio and compare competing reactor facility cadmium ratios when choosing reactor irradiation facilities to dope their silicon. Cintichem includes the silicon concern in its unique purpose exemption request because LEU conversion will harden the neutron spectrum, cause more silicon crystal defects, cause lower doping productivity, and therefore reduce the quality and quantity of the NTD silicon service irradiation program.

The above arguments pertaining to the disadvantages of converting to LEU (<20% U235 enrichment) reactor fuel will also apply to intermediate enrichment but it is difficult to say, without experimentation, what enrichment will be insignificant in every respect. Any change could be significant until it is proven not to be.

Cintichem has so far reviewed the technical problems associated with the conversion of the Cintichem reactor to LEU fuel and the detriment to the continuous and reliable supply of vital, short lived medical isotopes. Any one of these complications has the potential for causing eventual shortages; all of them combined will surely have a detrimental effect in the future.

III. ECONOMIC ISSUES

Cintichem understands that the NRC has indicated that economic benefit is not a basis for a unique purpose exemption, but when economic viability is one's raison d'etre and, without this viability the sole domestic supplier would cease operation, it then becomes a pertinent consideration for assuring the supply of a material which is vital for the national health and welfare.

In addition to these domestic concerns, the Cintichem facility is a net exporter of products and services which contribute positively to the U.S. Balance of Trade Payments. The loss of this facility would have the compound effect of the loss of income from current exports from the facility as well as from the purchase of all product and services that are currently distributed domestically

As an introductory comment to these commercial considerations Cintichem believes it important to note that the final rule on non-power reactor conversion to LEU fuel was expanded to include "commercial activity" in the definition of unique purpose. NRC Generic Letter 86-12 includes the "assurance of a domestic supply of some essential product" as a valid consideration for a unique purpose exemption. Any commercial enterprise is based primarily on the expectation that profit, return on investment, and growth will occur. Without these results there is no motive for sustaining a business. Cintichem believes that commercial viability must at least be a valid factor in determining whether a program can reasonably be continued by private enterprise without the use of HEU fuel.

The fuel fabrication estimate was provided by manufacturers who have had limited experience working with the relative higher density LEU loadings. Cintichem believes its reactor will require the highest density fuel loading (greater than 4.5 gm U/cc) in order to maintain present design metal/water ratio and fuel element burn up which is currently at > 50% of the fissionable material. This high density can only be achieved with silicide fuel and, since fuel fabricators have had no ongoing production experience with this process, this estimate could be inaccurate.

The waste disposal figure assumes that the transuranic content of the isotope production waste will increase due to the hardened neutron flux in the core. The current effective production cross section for Pu, including the resonance integral, has been measured to be approximately 2/3 the maximum that is theoretically possible but a factor of 2 above the thermal neutron capture cross section for this reaction. The difference is attributable to the resonance capture of epithermal neutrons. As the neutron flux spectrum hardens with LEU conversion, the Pu production increases. The amount by which it does has been conservatively estimated by applying the highest theoretical cross section. If the Pu content of the waste caused the waste classification to change from B to C it could lead to higher cost and reduced availability of disposal space. These details are unclear at this time.

1 Last known price of silicide fuel used in ORR
2 F.R. Vol. 51, No. 32 p.5754, 2/18/86

These are the cost elements of radioisotope production that Cintichem now predicts will increase as a result of converting the reactor fuel to LEU. The total estimated increase applies to the routine, direct, ongoing expense of production. Since it is estimated that the conversion to LEU fuel cannot be accomplished until 1989 or 1990, other factors could develop that cannot be anticipated now. Not included in the above estimate are the costs that Cintichem can foresee that will be involved in the initial reactor conversion. There will be man-years of work in revising technical specifications, safety analyses, licenses, operating procedures, and training documents in addition to the work of the actual conversion. The cost associated with product and waste reclassification previously described will also amount to a substantial initial cost. Also of note here is that NRC's Regulatory Analysis implied that the costs involved in an LEU conversion would only involve initial changeover costs. As discussed above, this increase is an ongoing cost carried on indefinitely after core conversion. If LEU is mandated at Cintichem, the Federal Government, in meeting its rule to fund facilities for all the costs of LEU conversion, should provide funding for the initial core conversion and ongoing annual subsidies to offset the higher production costs associated with LEU fuels. Cintichem also notes that the U.S. Department of Energy has notified us that Federal funding for a Cintichem LEU conversion will not be made available during fiscal year 1987 and that current D.O.E. plans only include initial funding and only for university reactor conversions. The D.O.E.'s February 11, 1987 letter addressing this subject is enclosed.

Other market considerations are that there are only a few major suppliers of reactor-produced radiochemicals in the world. Cintichem is the only commercial domestic supplier and participates in a world market against competitors who are subsidized by their governments or use government owned reactors. Cintichem's main competitors are AECL (Canada), IRE(Belgium), Australian Atomic Energy Agency and East Germany. It must be emphasized that this business is conducted as a separate and distinct entity from the radiopharmaceutical industry which it serves. The estimated cost increase will have to be fully absorbed within this business and it will be very recognizable by the pharmaceutical manufacturers, who are our customers. If competing producers are not subject to the same cost pressures, Cintichem would be at a definite disadvantage. Since Cintichem's competitors are not wholly commercial entities, and since they use higher powered, government owned test reactor facilities, Cintichem believes that it would be at a definite competitive disadvantage. Specifically, conversion to LEU in a low power reactor is more significant from the standpoint of production cost than it is in a high power reactor. Production batch sizes vary with core power level. The direct incremental cost of production is inversely proportional to production batch size. The direct incremental cost of production in a low power reactor, therefore, is a much higher fraction of the total cost than it is in higher power reactors. Assuming the fixed costs remain the same, the incremental cost to the producer with a low power reactor would be much greater than for the producer with the higher powered reactor and any decrease in process yield would be magnified in the cost experience of the lower powered reactor facility. A rationalization of the direct production cost of Mo99 in reactors of differing power levels is shown on Table D. In a commodity type business such as radiochemicals, margins are made and price is often based upon incremental direct production cost.

Cintichem has the lowest powered reactor of all the radioisotope producers and hence it will experience the highest direct production cost increase and it will be placed at a competitive disadvantage.

It is unlikely that the increase in cost could be compensated for by increasing prices because of the aforementioned competition. Cintichem, as a private business enterprise, requires profitability and growth to stay viable. The instantaneous and continuing economic consequences of converting to LEU reactor fuel could jeopardize its existence.

IV. CONCLUSION

In summary, Cintichem is applying for a unique purpose exemption from the requirements under 10 CFR Pt 50.64 to convert the reactor fuel from HEU to LEU for the following reasons:

1. Cintichem has a preeminent position as a commercial supplier of certain medical radioisotopes which are vital in the practice of nuclear medicine and that it is in the national interest to maintain this sole domestic supply capability.

2. It is imperative to the practice of nuclear medicine to have continuity of a ready and adequate supply of short-lived isotopes.

3. Conversion of the Cintichem reactor fuel to LEU will cause a reduction in isotope production capacity by at least 10% which will result in shortages of certain isotopes when other producers cannot supply their usual share to the market due to technical difficulties, as has happened in the past.

TABLE D

TABLE E

4. It will practically be impossible to requalify products and waste made in the Cintichem LEU core and simultaneously continue to supply product during the conversion process. Cintichem's failure to sustain its supply to its market segment will result in shortages within the U.S.A.

5. Cintichem will be at a competitive disadvantage because:

(a) Initial costs of conversion, such as relicensings, all associated changes in operating and training documentation, and the recharacterization of radioisotope products and waste, will not be subsidized under the current DOE funding plan. Competitors use reactors owned and operated by government agencies or consortia and they will be relatively unaffected by conversion costs of this kind.

(b) The ongoing added cost of production caused by lower yields and other cost elements previously mentioned are directly related to product and, because Cintichem's direct production cost is a higher portion of total production cost compared to suppliers using higher powered reactors, Cintichem will experience a greater cost increase than its competitors.

(c) Conversion to LEU reactor fuel will adversely affect reliability and efficiency of Cintichem services. These competitive disadvantages will impact negatively on Cintichem's success in the radiositope market. Cintichem relies on profitability and growth to justify its continuance.

In my opinion, conversion to LEU reactor fuel could be the cause for Cintichem's eventual discontinuance as a domestic source of medical radioisotopes.

Very truly yours,

J. J. McGovern
Senior Vice President

JJMcG:eb
enc.

Department of Energy
Washington, DC 20585

FEB 11 1987

Dr. William G. Ruzicka
Manager, Nuclear Operations
Cintichem, Inc.
P.O. Box 816
Tuxedo, New York 10987

Dea. Dr. Ruzicka:

In accordance with Nuclear Regulatory Commission Rule, 10 CFR Part 50, Limiting The Use of Highly Enriched Uranium in Domestically licensed Research and Test Reactors, you are hereby notified that Federal funding by the Department of Energy for conversion of your reactor will not be available during Fiscal Year 1987.

Current Department of Energy plans include funding for conversion of university owned reactors only. You will be notified if these circumstances change.

Sincerely,

Richard E. Stephens

Richard E. Stephens
Division of University & Industry Programs
Office of Field Operations Management
Office of Energy Research